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W81XWH-09-2-0102

TITLE:  
**Traumatic Brain Injury Diffusion Magnetic Resonance Imaging Research  
Roadmap Development Project**

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# REPORT DOCUMENTATION PAGE

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<b>14. ABSTRACT</b> Traumatic Brain Injury (TBI) is a public health problem of immense magnitude and immediate importance that has become endemic among military personnel and veterans. Imaging biomarkers of TBI are needed to support diagnosis and therapy and to predict TBI consequences while avoiding further injury. Diffusion magnetic resonance imaging has potential to become the non-invasive tool of choice for TBI structural assessment. Despite its potential, realizing the benefits of diffusion MRI in TBI requires a base of evidence for decision making that requires multi-organizational coordination and planning. The purpose of this proposed research is to synthesize a roadmap for diffusion MR imaging in brain traumatic injury that can advance the field and deliver the benefits most effectively in the shortest period of time. Essential steps toward implementation of the plan will be taken thereafter.					
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## INTRODUCTION

Traumatic Brain Injury (TBI) is a public health problem of immense magnitude and immediate importance that has become endemic among military personnel and veterans.

Imaging biomarkers of TBI are needed to support diagnosis and therapy and to predict TBI consequences while avoiding further injury. Diffusion magnetic resonance imaging has potential to become the non-invasive tool of choice for TBI structural assessment. Despite its potential, realizing the benefits of diffusion MRI in TBI requires a base of evidence for decision making that can only be assembled by multi-organizational coordination and planning.

The purpose of this research is to synthesize a roadmap for diffusion MR imaging in brain traumatic injury that can advance the field and deliver the benefits most effectively in the shortest period of time. Essential steps toward implementation of the plan will be taken to accelerate translation of the technology into clinical practice.

A roadmapping meeting was organized and conducted in June 2010 to assess state-of-the-art practice in brain traumatic injury imaging research and to propose specific recommendations regarding: (1) the standardization of diffusion imaging techniques, (2) the validation of the accuracy and clinical utility of imaging markers of the white matter injury, (3) the validation of imaging biomarkers relevant to clinical outcomes, and (4) the creation of a central repository to achieve these goals. This project implements a process to create these recommendations and examine practical steps to achieve them.

At present, an established medical method for quantitative, sensitive and specific evaluation of closed head traumatic brain injury does not exist. Many technologies are being utilized such as blood work, X-ray, computed tomography scan (CT Scan), magnetic resonance imaging (MRI), and electroencephalogram (EEG), but perhaps the most promising technology on the horizon is the Diffusion Tensor Imaging (DTI). Diffusion tensor imaging (DTI) is a new magnetic resonance imaging (MRI)-based technique that allows the visualization, location, and orientation, of the brain's white matter tracts to determine changes in the brain due to IED and related traumatic brain injuries. There is a critical and immediate need to use these tools to measure and track long term changes in the brain. The potential for DTI to improve our understanding of TBI has not been fully explored and challenges associated with non-existent standard practices amongst researchers and manufacturers remain a major challenge that this award will attempt to address through the design of a roadmap. Ultimately, imaging biomarkers for TBI may be identified, qualified and validated as a result of the roadmap.

On completion, this project will provide a 5-year roadmap for diffusion MR imaging for TBI achieved using a consensus process, with specific recommendations for imaging protocols, post-processing tools, quality control standards, and a shared image repository. The recommendations will be disseminated and pilot tested. A DTI of TBI post-processing workshop will be conducted. A testbed archive, informatics grid infrastructure, and post-processing software toolsets will be supported by practical implementations to guide further development and disseminate the technology.



## **BODY:**

Despite successful completion of more than 50 published early phase single center clinical trials of D-MRI of TBI, there is insufficient evidence and experience to justify use of this technology in clinical practice. All of the published studies are early phase (0, 1, 2) single center trials with relatively small sample sizes. In general, they lack standardization in the disease definition, imaging protocol, and measurement post-processing techniques. There has been little or no data sharing, post-processing is laborious and irreproducible at other centers, such the meta-analysis of these studies is difficult and as a body of work, they cannot satisfy evidence criteria for widespread use.

The promise of advanced imaging for disease assessment and monitoring has generated many initiatives on imaging biomarkers, but TBI isn't included. As a broad generalization, D-MRI of TBI is not acceptable for clinical applications. But this could change if it were appropriately further developed and tested in a successful multicenter clinical trial.

In 2009, the Joint DoD-VA Clinical Guidelines did not include D-MRI due to lack of evidence to support its adoption and widespread use. As a consequence, D-MRI methods and technology remain as research tools only, despite their promise as a potential imaging biomarker for TBI. However, current testing methods are unable to detect and quantify TBI as a disease, predict outcome, guide and monitor therapy. Despite similar obstacles, other neurological disorders have made great progress in the introduction of advanced imaging technology and adoption of biomarkers, including acute stroke, brain tumors, and Alzheimer's disease.

As part of a long term solution, there is need to develop D-MRI into a qualified and validated biomarker by adapting methods and using best practices for other neuroimaging biomarkers. We are engaged in identifying the barriers to progress, especially for multidisciplinary (MRI physics, computer science/image processing, and especially TBI clinical practice) collaboration. A vanguard project is needed to conduct multicenter trial and establish infrastructure needed for Phase 3 studies of TBI using D-MRI, so we are working toward that end.

### **Biomarkers**

Borrowing formal definitions & processes adopted by FDA (and other agencies) that were initially defined for pharmacogenetics, and more recently employed in many biomarker applications (cancer, vascular, degenerative,...) we adopt these concepts and use them for TBI. The notion of imaging biomarkers is motivated by "critical path" concerns of FDA-industry as expressed in the 2004 white paper on "

### **Imaging Biomarkers**

Biochemical and molecular markers have revolutionized medicine and drug development in recent decades, giving clinicians and researchers the opportunity to infer biological states in patients and in response to drug interventions. For example, the blood of HIV patients can be tested for its viral load to assess the course of their disease, as well as providing a surrogate endpoint for trials of anti-HIV drugs. Now imaging biomarkers are coming into their own,

offering earlier detection of some diseases than molecular markers and enabling practitioners to see into the body without the need for invasive procedures — of great benefit to clinicians and patients.

Imaging Biomarkers are central elements of FDA's Critical Path Initiative where new biomarkers are discovered, evaluated, qualified and validated. Biomarkers may be physiological, serum, genetic, and recently, imaging.

Consortia of industry-academia and government have been formed to facilitate imaging biomarker development and include QIBA = Quantitative Imaging Biomarkers Alliance, UPICT = Uniform Protocols for Imaging in Clinical Trials, CTSA = Clinical Translational Science Award (imaging working group – IWG). As an example, professional societies have organized special sessions at their annual meeting, such as CDMRI'10 - MICCAI 2010 Workshop on Computational Diffusion MRI . to encourage progress in this key area.

Neuroscience Biomarkers have grown in importance and were the focus of an Institute of Medicine advisory group report that highlights their potential importance and outlines the steps needed to develop them.

Prior workshops on TBI sponsored by DoD & other government agencies focused on defining the need, requirements of clinical practice, and engagement of academia as well as industry. We use the same strategy to organize and conduct an interdisciplinary workshop to review prior work and define current status, identify needs & requirements from multiple perspectives. We sought to describe and apply best practices by drawing on the grater Neuroimaging community (stroke, Alzheimer's disease, neurooncology) experience with similary planning.

We recruited a broad spectrum of experts from Academia, Government, and Industry and challenged them with the following observations:

- Validated and Qualified Biomarkers are critical to optimizing Traumatic Brain Injury (TBI) disease management
- New imaging methods, diffusion MRI is an example, are promising candidates for TBI disease biomarkers
- There are no qualified or validated imaging biomarkers for TBI
- Development of imaging biomarkers for other neurological conditions is more advanced: neuro-oncology, stroke, and neurodegenerative disorders (e.g., Alzheimer's disease)
- Borrowing on experiences in other related disciplines, an imaging biomarker vanguard project for D-MRI of TBI can be designed

## **D-MRI of TBI Workshop**

Using support from this project, we conducted a Workshop:

- International workshop on diffusion MRI of TBI – Roadmap development
  - Chicago, IL –2-3 June 2010
  - Invited attendance of 60
  - 3 themes/breakout groups: 15 experts/group

Planning is underway currently for a future 2<sup>nd</sup> workshop (at MICCAI or ISMRM 2011) on post-processing D-MRI image analysis of TBI. We observed that many of the world's leading groups on post-processing of D-MRI focus only on "normal" brain scans, and seek to substituted-MRI scans of repeat trauma as an

## **Infrastructure needs**

By conducting these workshops, we can learn the infrastructure needs for a larger effort that can surpass the low impact of previously conducted early phase clinical trials. To date, we begin to appreciate the need to address three important issues to ensure long term success. These issues include:

- Access to data
  - Data sharing initiative, requested from all groups who published results on D-MRI of TBI
  - Open access to our own data
- Informatics infrastructure
  - Capable of supporting multicenter trials
  - Site qualification, quality control center
  - Multi-site data analysis
- MRI data acquisition
  - Testing MRI scanner protocols, reproducibility
  - Phantom testing and quality control
  - Industrial liaison

## **Validation Strategy**

Formal criteria for evaluation of biomarkers have been defined, especially for tissue and serum markers. For example, the Biomarker Readiness Level (BRL) definitions were adapted from DoD Technology Readiness criteria and applied to serum (in vitro) testing. We will adopt this well developed framework to track progress in developing TBI imaging biomarker(s), such as diffusion MRI (D-MRI). The FDA biomarker qualification process is a suitable model, now that experience was gained in its application to a variety of new agents and technologies.

DoD pioneered the development and application Technology Readiness Levels, a scale that describes the maturity of a technology with respect to a particular use:

- Scale from 1 (least mature) to 9 (most mature)
- Heuristics:
  - TRL 1 = “an idea”
  - TRL 4 = “a lab experiment”
  - TRL 6 = “a prototype ready for initial integration”
  - TRL 7 = “ready for final operational testing”
  - TRL 9 = “fielded and used as intended”

We plan to apply the related “Biomarker Readiness Levels” to D-MRI of TBI to gauge the maturity of imaging for this specific application. The notion of Biomarker Readiness Level (BRL) has been used by the National Cancer Institute for tissue and serum biomarker development, but its use in imaging biomarkers will be new.

### **Challenges**

Among the most important challenges that we currently face is data sharing – both sociological and confidentiality issues - since such practice is not accepted and widespread at present. This is a serious impediment to progress, however, especially from the perspective of the image visualization and analysis community. Given the essential role of IRBs (many), HIPAA restrictions and need for HRPO oversight and approval, we are looking for means of simplifying and streamlining the application process. To enable widespread data sharing, it is essential to consider individual rights, variations among multiple institutions who collect the data, and review of suitable models in use for retrospective review for other disease processes and clinical trials.

D-MRI post-processing is a critical element of potential TBI applications, with methods development fueled by access to data. If we succeed in liberating TBI datasets, this could attract a large community of developers to refine and perfect the tools needed to analyze the MRI scans. At the June workshop we learned that there is potential for performing data analysis at multiple sites while the trial is underway.

Data acquisition refinements cannot be neglected, due to fundamental differences in various imaging platforms (MRI scanners are produced by GE, Siemens, and Philips. All are mutually incompatible in design and execution.).

The sources of variation in MRI scans obtained with D-MRI are not well understood and characterized, so our future work is focused on this issue as well. We appreciate the need for phantom and reproducibility data and are expending effort to resolve the issue. Closely related are the requirements to establish quality control review of new data and to establish criteria for site qualification in future D-MRI of TBI trials.

**Next Funding Period**

The goals for the next year include definition of the willingness and ability of TBI imaging community to share their data, as we complete a meta-analysis of their prior work. We will assemble a test data set to enable post-processing workshop, as we document the data sharing issues in this arena.

Recognizing that new TBI common data elements are available, they need to be implemented and tested in clinically realistic environment. Doing so, we can determine, 1) Are they sufficient? 2) Are they practical? Practical use of the CDEs will encourage their widespread adoption.

We expect to be able to test phantoms and human volunteers on all 3 major MRI scanner platforms where we use the “recommended” protocol from our June 2010 workshop. In this, we can test immediate and short term reproducibility within and between platforms. Evaluation of candidate phantoms (existing and new) will be done. The organization and presentation of a multi-institutional post-processing workshop focused on practical tools for TBI data processing of D-MRI scans is unprecedented. To accomplish this we need data sets and must have formal evaluation tool(s). We can thereby test the infrastructure for multi-site image analysis and data quality control.

Several multicenter TBI imaging projects are underway or planned, but not all are documented in [clinicaltrials.gov](http://clinicaltrials.gov). We intend to reach out and contact / visit as many as possible to inform them of roadmap workshop results and engage them in the process.

## **KEY RESEARCH ACCOMPLISHMENTS:**

In the first year, we were able to complete the following:

1. A workshop was organized and convened to develop a roadmap for application of diffusion MRI to traumatic brain injury with input from multidisciplinary domain experts.
2. The workshop was recorded on digital audio and video. The presentations at the workshop were edited and have been prepared for dissemination on a website.
3. A summary roadmap report was drafted and is being edited, with intention to publish the document in a major peer-reviewed journal.
4. More than 60 experts participated in the conference, and their detailed biographies, key publications, and contact information was compiled with the intent to disseminate the information through the same website as the presentations given at the workshop.
5. A comprehensive survey of early phase clinical trials that applied diffusion MRI to TBI was done, the references compiled and summarized, and all of the corresponding authors were surveyed to determine their willingness to share image data.
6. Infrastructure, documentation and training materials required to translate new diffusion MRI technology developments in data acquisition and image post-processing into clinical practice have been drafted for website dissemination.
7. In preparation for experiments conducted using phantoms and human volunteers to evaluate sources of variability and stability in MRI scanners and to validate the longitudinal evaluation of traumatic changes in brain white matter using diffusion MRI (D-MRI), we applied and completed the necessary IRB and HRPO review processes to gain approval so this work can commence.

## **REPORTABLE OUTCOMES:**

***M. Vannier, et al. Diffusion MRI of traumatic brain Injury roadmapping project***, CARS 2010 annual meeting, Geneva, 26 June 2010. Published in Int J CARS (2010) 5 (Suppl 1):S39-S44.

## **CONCLUSION:**

Diffusion MRI of neurological/neuropsychiatric disorders (chronic TBI, PTSD, and related disorders) is an important potential market for the imaging industry. Virtually all individuals with traumatic brain injuries – including all ages are potential candidates – whether injury is due to auto, sports, combat, falls or other. Serum protein changes after trauma, optical imaging methods, PET/SPECT with radioisotope agents, and other technologies are less generally available or have known limitations. No “one size fits all”, given the diversity of patients and injuries. By preparing the infrastructure needs and facilitating interactions among diverse experts in TBI and related disciplines, the translation of promising D-MRI technology into clinical practice based on a solid body of evidence can be accomplished.



## **REFERENCES:**

1. VA/DoD Clinical Practice Guideline For Management Of Concussion/Mild Traumatic Brain Injury (mTBI) . Version 1.0 – 2009
2. *M Davis, S Hanson, B Altevogt, Rapporteurs, Forum on Neuroscience and Nervous System Disorders*. Institute of Medicine, National Academy of Sciences. Neuroscience Biomarkers and Biosignatures: Converging Technologies, Emerging Partnerships. (2008)
3. Summary of meeting proceedings. Non-Impact Blast-Induced Traumatic Brain Injury. 12-14 May 2009.
4. F. Goodsaid and F. Frueh. Biomarker qualification pilot process at the US Food and Drug Administration. AAPS Journal, (9) 1, 2007.

## **APPENDICES:**



**Slide set from Program Line Review on 21 September 2010.**

**Briefing book for the 2-3 June 2010 Workshop, Chicago, IL.**

  
  
Product Line  
Review  
(PLR)  
Meeting  
  
Medical  
Imaging  
  
21 Sept 2010  
  
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# Traumatic Brain Injury Diffusion Magnetic Resonance Imaging Research Roadmap Development Project


**Michael W. Vannier, MD**  
**14 September 2009 – 13 October 2012**  
**\$2,122,000**  
**Type of Funding - CSI**

  
  
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# Military relevant issue to be solved

- **Goal:** Translate diffusion MRI for TBI into a qualified clinical imaging biomarker
- **Aims:**
  - Develop consensus roadmap for diffusion MRI physics and image processing methods to provide sensitive and specific marker for mild to moderate traumatic brain injury (TBI)
  - Automate post-processing of D-MRI for TBI and conduct workshop(s) on comparative evaluation of methods
  - Design, develop and test infrastructure to support Phase 3 multicenter clinical trials of D-MRI for TBI (protocols, site qualification, quality control, record-keeping, ...)
  - Develop web-based image archive and support data sharing of D-MRI database





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Imaging**


**21 Sept 2010**

# Disconnection


3


- **D-MRI of TBI**
  - More than 50 single center studies completed
  - All are early phase (0, 1, 2) with small sample sizes
  - No standardization
    - Disease definition
    - Imaging protocol
  - No data sharing
  - Post-processing is laborious and irreproducible
  - Difficult meta-analysis
  - Does not meet evidence criteria for widespread use

- Many initiatives on Imaging Biomarkers, but TBI isn't included.




Quantitative Imaging Biomarkers Alliance







**THE biomarkers  
CONSORTIUM**



**CRITICAL PATH  
INSTITUTE**  
Improving the Path for Innovative Therapies





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### Solution

Develop D-MRI into a qualified and validated biomarker


- by adapting methods and using best practices for other neuroimaging biomarkers
- identifying the barriers to progress, especially for multidisciplinary (MRI physics, computer science/image processing, and especially TBI clinical practice) collaboration
- vanguard project to conduct multicenter trial and establish infrastructure needed for Phase 3 studies of TBI using D-MRI

In other words, to focus on the Critical Path and translate D-MRI into clinical practice

  
  
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### Biomarkers



- Borrowing formal definitions & processes adopted by FDA (and other agencies)
  - Initially defined for pharmacogenetics, and now for many other applications (cancer, vascular, degenerative,...) of biomarkers
  - Motivated by “critical path” concerns of FDA-industry

  
NATURE BIOTECHNOLOGY VOLUME 28 NUMBER 5 MAY 2010  

#### Biomarkers on a roll

A consortium of industry, nonprofit institutions and regulators outlines a rolling biomarker qualification process, providing the first clear path for translation of such markers from discovery to preclinical and clinical practice.



  
The 6th Annual Biomarkers Congress  
[www.biomarkers-congress.com](http://www.biomarkers-congress.com)  
  
Over 200 industry delegates  
Over 55 presentations/roundtables/panel discussions  
4 interactive streams  
Biomarkers Discovery & Validation Strategies & Regulations  
Comparative Diagnostic & Stratified Medicine  
Safety & Biomarkers in Clinical Development  
Enabling Technologies to Maximize Biomarker Identification

  
  
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## Imaging Biomarkers


- Biochemical and molecular markers have revolutionized medicine and drug development in recent decades, giving clinicians and researchers the opportunity to infer biological states in patients and in response to drug interventions. For example, the blood of HIV patients can be tested for its viral load to assess the course of their disease, as well as providing a surrogate endpoint for trials of anti-HIV drugs.
- Now imaging biomarkers are coming into their own, offering earlier detection of some diseases than molecular markers and enabling practitioners to see into the body without the need for invasive procedures — of great benefit to clinicians and patients.

From: Thompson Reuters. The promise of imaging biomarkers. White paper. 2010.


  
  
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## Critical Path Initiative

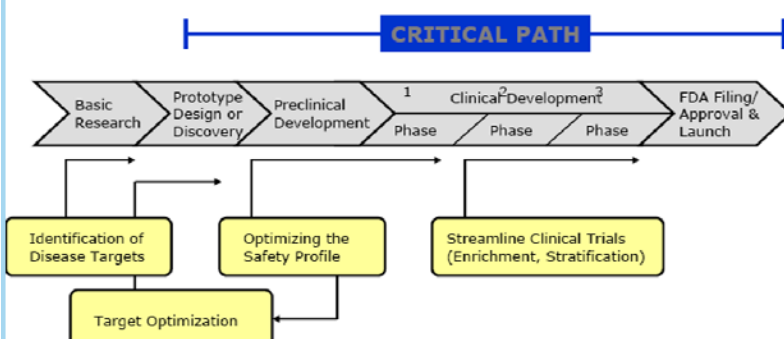
Began in 2004, in response to FDA white paper that noted impediments (time & cost) for translation of new products to reach patients.





Challenge and Opportunity on the Critical Path to New Medical Products



U.S. Department of Health and Human Services  
Food and Drug Administration  
March 2004



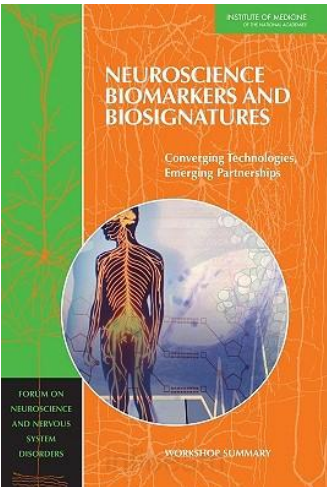
<http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/>

  
  
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## CPI Progress to Date

- New biomarkers are discovered, evaluated, qualified and validated.
  - Biomarkers may be physiological, serum, genetic, and recently, imaging.
- Consortia have been formed to facilitate imaging biomarker development:
  - QIBA = Quantitative Imaging Biomarkers Alliance
  - UPICT = Uniform Protocols for Imaging in Clinical Trials
  - CTSA = Clinical Translational Science Award (imaging working group – IWG)
  - CDMRI'10 - MICCAI 2010 Workshop on Computational Diffusion MRI
  - And many others...

## Neuroscience Biomarkers



[IOM 2008]

Biological markers, or biomarkers, are quantitative measurements that provide information about biological processes, a disease state, or about response to treatment, providing insight into preclinical and clinical data.

Biomarkers hold the potential of a better understanding of the etiology and pathogenesis of a given disorder, providing insight into diagnosis, treatment, and prognosis for many debilitating disorders and diseases.

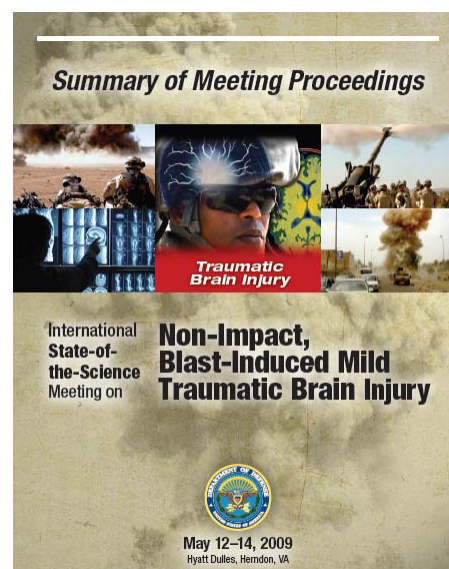
## DESIRABLE CHARACTERISTICS OF BIOMARKERS IN PSYCHIATRY

- Test reliability, accuracy, and limitations are well characterized
- Biomarker development process is clearly disclosed
- Findings are reproducible with independent replication and peer review
- Interpretative framework for biomarker allows comparison with other neurobiologic observations
- Information provided by the biomarker is timely, clinically useful, and cost effective
- Technology is available and well tolerated by target patient population
- Methodology can be integrated into clinical care practice patterns

Cook IA. *Primary Psychiatry*. Vol. 15, No 3. 2008.

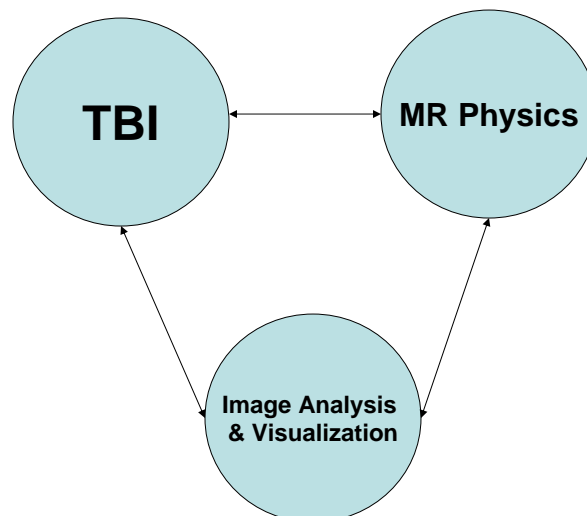
## Prior Workshops

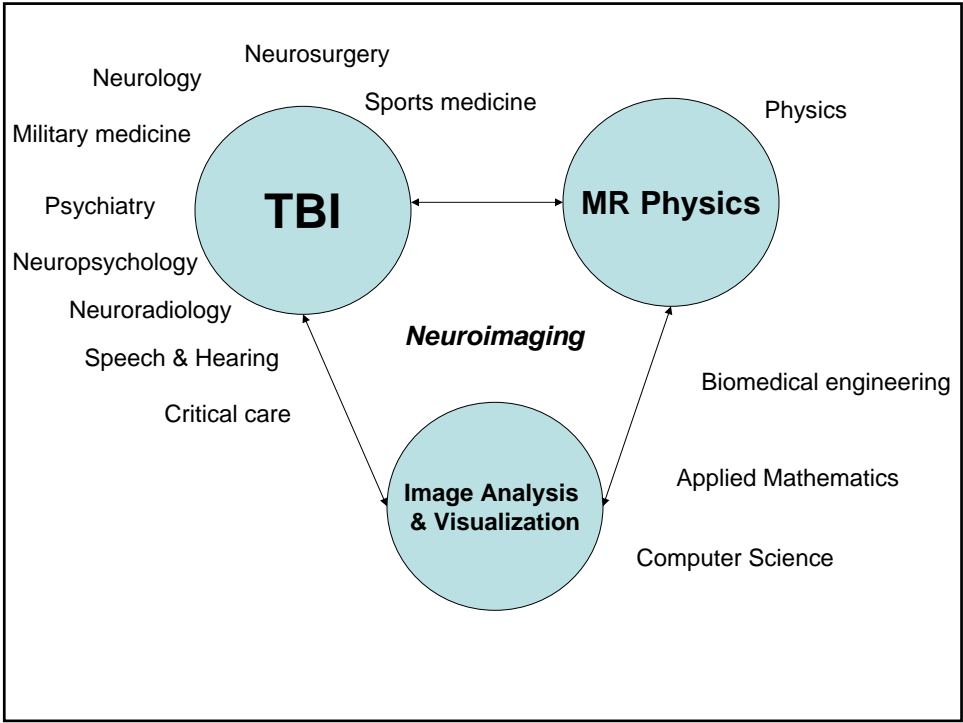
- Stroke Imaging
- ADNI
- Neuro-oncology
- TBI



## Approach

- Interdisciplinary workshop
- Review prior work and define current status
- Define needs & requirements
- Multiple perspectives: DoD & government agencies, clinical practice, academia, industry
- Describe and apply best practices
  - Neuroimaging (stroke, Alzheimer's disease, neurooncology)
- Share data





- Experts
- DoD – DVIBC
  - DoD – DARPA
  - DoD - TATRC
  - USMC
  - VA Headquarters
  - NIH (NIBIB, NCI, NICHD, NINDS, NIDA)
  - NIST
  - FDA
  - Univ of Antwerp – Belgium
  - Univ of Utrecht
  - INRIA

- GE
  - Philips
  - Univ of Utah
  - Univ of Penn
  - Stanford Univ
  - Duke Univ
  - MGH
  - Brigham & Womens
  - Johns Hopkins
  - Dartmouth
  - Washington Univ
  - Harvard Univ
  - Cleveland Clinic

- Loma Linda Univ.
  - Wayne State Univ
  - Univ of Michigan
  - Univ of Wisconsin
  - Med College of Wisc
  - Univ of Minnesota
  - Univ of Virginia
  - UCSF
  - Brown University
  - San Francisco VAMC
  - Boston VAMC
  - Vanderbilt Univ
  - Brain Trauma Fdn.



## Academia, Government, Industry

- University Medical Centers (16 states in USA)
- International (France, Germany, Belgium, The Netherlands)
- Government: DoD (US Army, DARPA, Marine Corps), NIH (5 Institutes), VA, NIST, FDA
- Industry: GE, Philips

Approx. 60 invited guests

Experts in D-MRI, image analysis/visz, and/or TBI





### Workshop Group:

#### **TBI - MRI Physics - Image Analysis & Visualization**

- 60 experts – approximately 20 in each domain area
- Academia – Government – Industry
- By invitation
- Open didactic sessions with 40 presentations
- Closed breakout sessions in each topic area





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### Project Description



**Validated and Qualified Biomarkers are critical to optimizing Traumatic Brain Injury (TBI) disease management**

**New imaging methods, diffusion MRI is an example, are promising candidates for TBI disease biomarkers**

**There are no qualified or validated imaging biomarkers for TBI**

**Development of imaging biomarkers for other neurological conditions is more advanced: neuro-oncology, stroke, and neurodegenerative disorders (e.g., Alzheimer’s disease)**

**Borrowing on experiences in other related disciplines, this is an imaging biomarker vanguard project**



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### Workshop(s)

- **International workshop on diffusion MRI of TBI – Roadmap development**
  - Chicago, IL –2-3 June 2010
  - Invited attendance of 60
  - 3 themes/breakout groups: 15 experts/group
  - Results to be reported at international meetings in summer/fall 2010-11 & journal articles
- **2<sup>nd</sup> workshop (at MICCAI or ISMRM 2011) on post-processing D-MRI image analysis of TBI**

  
  
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### Infrastructure needs

- Access to data
  - Data sharing initiative, requested from all groups who published results on D-MRI of TBI
  - Open access to our own data
- Informatics infrastructure
  - Capable of supporting multicenter trials
  - Site qualification, quality control center
  - Multi-site data analysis
- MRI data acquisition
  - Testing MRI scanner protocols, reproducibility
  - Phantom testing and quality control
  - Industrial liaison

  
  
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### Validation Strategy

Formal criteria for evaluation of biomarkers have been defined

Biomarker Readiness Level (BRL) were adapted from DoD Technology Readiness criteria and applied to serum (in vitro) testing

Well developed framework to track progress in developing TBI imaging biomarker(s), such as diffusion MRI (D-MRI)

The FDA biomarker qualification process is a suitable model, now that experience was gained in its application to a variety of new agents and technologies

  
  
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*The AAPS Journal* 2007; 9 (1) Article 10 (<http://www.aapsj.org>).

*Themed Issue: Role of Biomarkers in Drug Development*  
*Guest Editors - Brian P. Booth and Jogarao V. Gobburu*

### Biomarker Qualification Pilot Process at the US Food and Drug Administration

*Submitted: January 2, 2007; Accepted: February 27, 2007; Published: March 23, 2007*

Federico Goodsaid<sup>1</sup> and Felix Frueh<sup>1</sup>

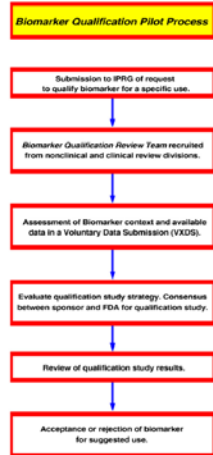
<sup>1</sup>Genomics Group, Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research, US Food and Drug Administration, 10903 New Hampshire Avenue, Building 21, Room 3663, Silver Spring, MD 20903-0002

**ABSTRACT**

New biomarkers of safety and efficacy are becoming powerful tools in drug development. Their application can be accelerated if a consensus can be reached about their qualification for regulatory applications. This consensus requires a review structure within the US Food and Drug Administration (FDA) that can evaluate qualification data for these biomarkers and determine whether these biomarkers can be qualified. A pilot process and corresponding Biomarker Qualification Review Team have been developed to test how the FDA can work on biomarker qualification.



The FDA pharmacogenomics guidance defines a valid biomarker as “a biomarker that is measured in an analytical test system with well-established performance characteristics and for which there is an established scientific framework or body of evidence that elucidates the physiologic, toxicologic, pharmacologic, or clinical significance of the test results.”

**Biomarker Qualification Pilot Process**





```
graph TD; A[Submission to IPHD of request to qualify biomarker for a specific use.] --> B[Biomarker Qualification Review Team recruited from nonclinical and clinical review divisions.]; B --> C[Assessment of Biomarker context and available data in a Voluntary Data Submission (VDS)]; C --> D[Evaluate qualification study strategy. Consensus between sponsor and FDA for qualification study.]; D --> E[Review of qualification study results.]; E --> F[Acceptance or rejection of biomarker for suggested use.];
```

Figure 1. Biomarker qualification pilot process at the US Food and Drug Administration

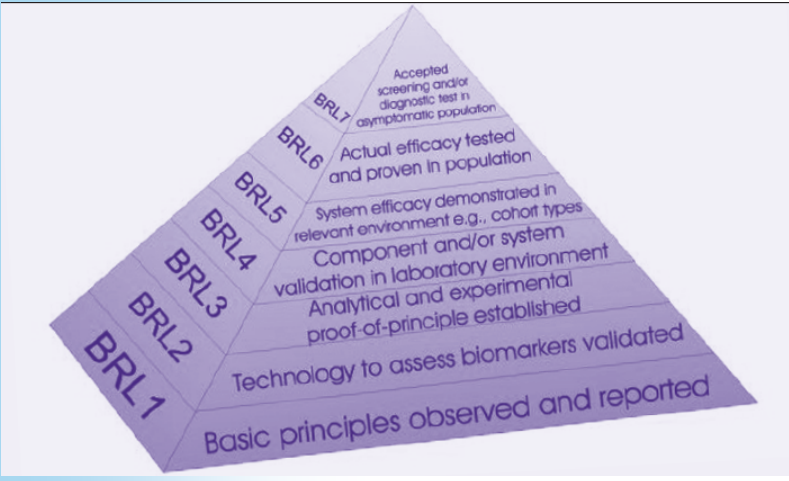
  
  
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## Validation Strategy

- **Technology Readiness Levels** are a scale that describes the maturity of a technology with respect to a particular use
  - Scale from 1 (least mature) to 9 (most mature)
  - Heuristics:
    - TRL 1 = “an idea”
    - TRL 4 = “a lab experiment”
    - TRL 6 = “a prototype ready for initial integration”
    - TRL 7 = “ready for final operational testing”
    - TRL 9 = “fielded and used as intended”
- We intend to apply “Biomarker Readiness Levels” to D-MRI of TBI to gauge the maturity of imaging for this specific application

  
  
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## Biomarker Readiness Level (BRL)



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With the assistance of the National Aeronautics and Space Administration (NASA) Jet Propulsion Laboratory, the Early Detection Research Network (EDRN) has adapted an engineering approach to ascertaining biomarker readiness level (BRL) in biomarker discovery and development.



S. Srivastava. *Gastrointest Cancer Res* 1(suppl 2): S60–S63.



  
  
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## D-MRI Data Acquisition & Quality Control



### Research/Development Timeline



ID	Task Name	Duration	Start	Finish	4th Quarter	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter										
					Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
1	<b>Roadmap Development</b>	266 days	Mon 9/14/09	Mon 9/20/10															
2	Define Panel and Agenda																		
3	Select experts	1 mon	Tue 9/15/09	Mon 10/12/09															
4	Invite expert participation	1 mon	Tue 10/13/09	Mon 11/9/09															
5	Review expert panels	2 wks	Tue 11/10/09	Mon 11/23/09															
6	Fill missing positions	2 mons	Tue 11/24/09	Mon 1/18/10															
7	Establish working agenda	1 wk	Tue 9/15/09	Mon 9/21/09															
8	Define overall schedule	2 wks	Tue 1/19/10	Mon 2/1/10															
9	Local Arrangements																		
10	Coordinate Expert Panels & Event Planning																		
11	Monthly teleconferences	9 mons	Tue 9/22/09	Mon 5/31/10															
12	Formulate questions	3 mons	Tue 9/22/09	Mon 12/14/09															
13	Distribute for comment	1 mon	Tue 12/15/09	Mon 1/11/10															
14	Review and approve questions	1 wk	Tue 1/12/10	Mon 1/18/10															
15	Establish agenda	1 mon	Tue 1/19/10	Mon 2/15/10															
16	Review and approve agenda	1 wk	Tue 2/16/10	Mon 2/22/10															
17	Distribute agenda	1 mon	Tue 2/23/10	Mon 3/22/10															
18	<b>Diffusion MRI of TBI Workshop</b>																		
19	Conduct meeting	0.8 wks	Tue 6/1/10	Fri 6/4/10															
20	Draft report	2 mons	Mon 6/7/10	Fri 7/30/10															
21	Circulate for comments	1 mon	Mon 8/2/10	Fri 8/27/10															
22	Make necessary edits	2 wks	Mon 8/30/10	Fri 9/10/10															
23	Distribute to participants	1 mon	Mon 9/13/10	Fri 10/8/10															
24	Finalize report with recommendations	1 wk	Mon 10/11/10	Fri 10/15/10															
25	Disseminate publicly	1 wk	Mon 10/18/10	Fri 10/22/10															
26	Publish report(s)	1 mon	Mon 10/18/10	Fri 11/12/10															
27	<b>Roadmap Completion</b>	1 day	Tue 11/30/10	Tue 11/30/10															

 	
<b>Product Line</b>	<h3>Successes to Date</h3>
<b>Review (PLR) Meeting</b>	<ul style="list-style-type: none"><li>■ Completed roadmap workshop and reported results at CARS'2010 meeting<ul style="list-style-type: none"><li>– Video and audio recordings have been edited</li><li>– Disseminate results via website</li><li>– Document and publish summary</li></ul></li><li>■ Surveyed all corresponding authors of D-MRI of TBI studies<ul style="list-style-type: none"><li>– Compiled results of data sharing survey</li><li>– Meta-analysis of published reports</li></ul></li><li>■ Developed candidate protocol for 2 of 3 major platforms (Philips and GE).<ul style="list-style-type: none"><li>– Ready for testing on humans, subject to IRB/HRPO approvals</li></ul></li></ul>
<b>Medical Imaging</b>	
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<b>Product Line</b>	<h3>Challenges</h3>
<b>Review (PLR) Meeting</b>	<ol style="list-style-type: none"><li>1. Data sharing – both sociological and confidentiality issues<ol style="list-style-type: none"><li>1. Under the control of IRBs (many) and HRPO</li><li>2. Individual rights; multiple institutions</li><li>3. Few good models to use for retrospective review</li></ol></li><li>2. Post-processing – methods development is fueled by access to data<ol style="list-style-type: none"><li>1. Performing data analysis at multiple sites while the trial is underway is new</li></ol></li><li>3. Data acquisition – fundamental differences in various imaging platforms<ol style="list-style-type: none"><li>1. Sources of variation are not well understood and characterized</li><li>2. Need for phantom and reproducibility data</li><li>3. Establish quality control of new data</li><li>4. Establish criteria for site qualification</li></ol></li></ol>
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29	<h3>What's Next</h3> <ol style="list-style-type: none"><li>1. Define the willingness and ability of TBI imaging community to share their data<ol style="list-style-type: none"><li>1. Complete a meta-analysis of prior work</li><li>2. Assemble a test data set to enable post-processing workshop</li><li>3. Document the data sharing issues in this arena</li></ol></li><li>2. New common data elements are available, but need to be implemented and tested in clinically realistic environment<ol style="list-style-type: none"><li>1. Are they sufficient?</li><li>2. Are they practical?</li></ol></li><li>3. Test phantoms and human volunteers on all 3 major MRI scanner platforms<ol style="list-style-type: none"><li>1. Use "recommended" protocol</li><li>2. Test immediate and short term reproducibility within and between platforms</li><li>3. Evaluate phantoms (existing and new)</li></ol></li><li>4. Post-processing workshop – need data sets and evaluation tool(s)<ol style="list-style-type: none"><li>1. Test infrastructure for multi-site analysis; quality control</li></ol></li></ol>

	
	
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30	<h3>Compare Competing Solutions</h3> <p>What relevant ongoing solutions are being pursued by others?</p> <p>Several multicenter TBI imaging projects are underway or planned. Not all are documented in <a href="http://clinicaltrials.gov">clinicaltrials.gov</a></p> <p>We intend to reach out and visit as many as possible to inform them of roadmap workshop results and engage them in the process.</p> <p>Describe the market(s), if applicable:</p> <ul style="list-style-type: none"><li>■ Diffusion MRI of neurological/neuropsychiatric disorders (chronic TBI, PTSD, and related disorders)</li><li>■ Virtually all individuals with traumatic brain injuries – including all ages are potential candidates – whether injury is due to auto, sports, combat, falls or other.</li><li>■ Serum protein changes after trauma, optical imaging methods, PET/SPECT with radioisotope agents, and other technologies are less generally available or have known limitations. No “one size fits all”, given the diversity of patients and injuries.</li></ul>



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### Intellectual Property / Publications Deriving from this Project

List any Confidentiality Agreements – MRI manufacturers require such agreements to program the scanners with new pulse sequences, but these restrictions are minor and don’t limit TBI research significantly.



Patents Filed -

- ❖ No patents.

List Invention Disclosures Submitted: None

List all Publications deriving from the project:

**M. Vannier, et al. Diffusion MRI of traumatic brain Injury roadmapping project**, CARS 2010 annual meeting, Geneva, 26 June 2010. Published in Int J CARS (2010) 5 (Suppl 1):S39-S44.



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Review (PLR) Meeting

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### Transition/ Business/ Marketing Plan

Describe plan, if applicable: N/A

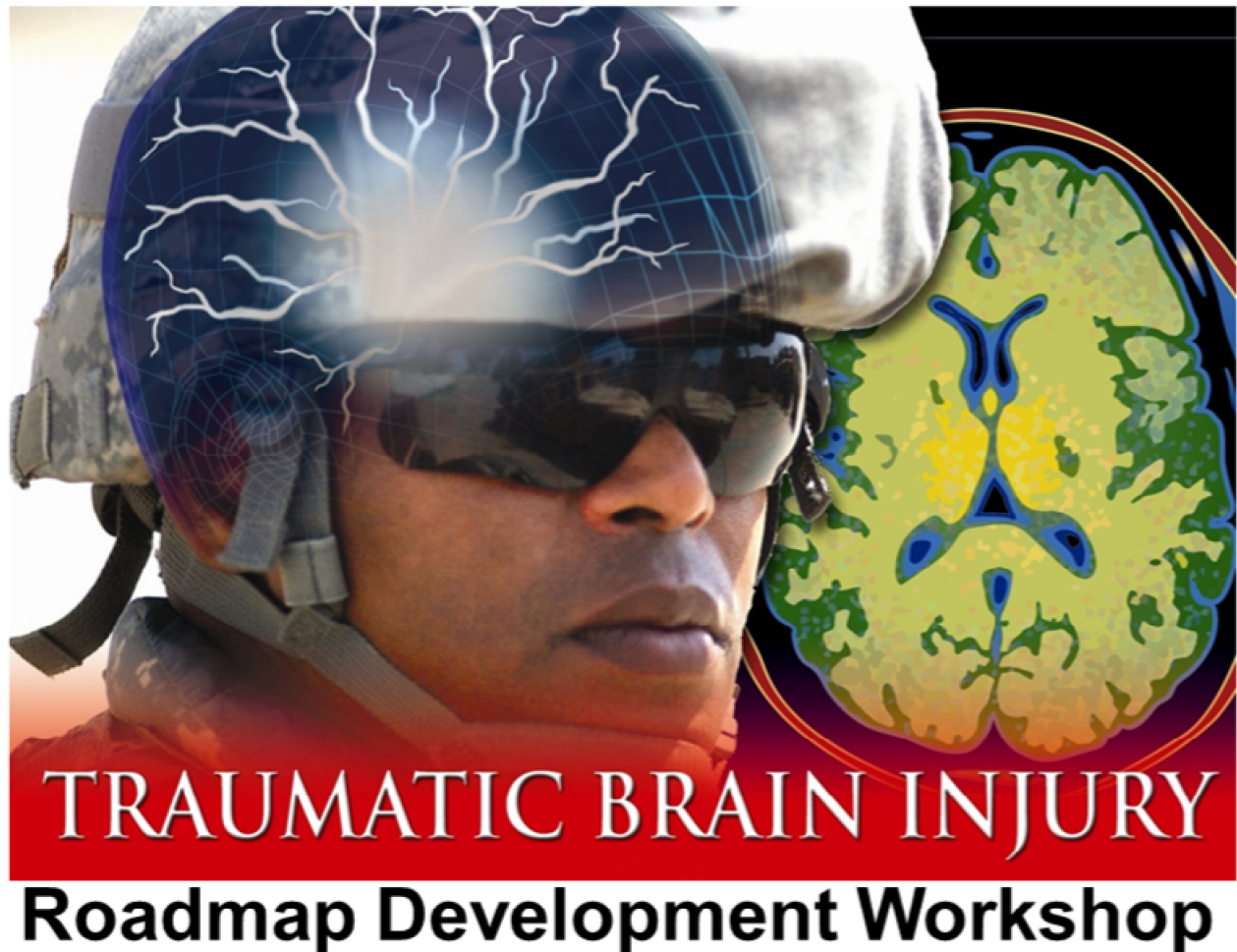


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<b>Project Funding</b>			
<b>Product Line</b>	<b><u>Current Budget</u></b>	<b><u>Expended Funds</u></b>	<b><u>%</u></b>
<b>Review (PLR) Meeting</b>	\$530,944	\$307,208	60%
<b>Medical Imaging</b>	<p>Note: Direct costs only. Delayed billing by conference site contractors and related travel expenses were received, approved and posted late, and are incomplete. UIC subcontract and MRI human studies were also delayed by HRPO/IRB approval process.</p>		
<b>21 Sept 2010</b>	<b>Other Funding if applicable:</b>		
<b>33</b>	<b>None.</b>		

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<b>Additional Project Information</b>	
<b>Product Line</b>	<b>Lab/Company/Group: University of Chicago</b>
<b>Review (PLR) Meeting</b>	<b>Principal Investigator: Dr. Michael Vannier</b>
<b>Medical Imaging</b>	<b>Government COR: Dr. Anthony Pacifico</b>
	<b>Government Project Officer: Laurie Haines</b>
	<b>Contract Instrument: Cooperative Agreement</b>
	<b>Period of Performance: 14 September 2009 – 13 October 2012</b>
<b>21 Sept 2010</b>	<b>Contract Specialist: Lisa Sawyer</b>
	<b>EDMS# : 3906</b>
	<b>Contract #: W81XWH0920102</b>
<b>34</b>	<b>** To Be Completed by COR or Project Officer</b>



# Diffusion MRI for



**Omni Hotel, Chicago**  
**2-3 June 2010**



THE UNIVERSITY OF  
**CHICAGO**

**UIC** COLLEGE OF  
UNIVERSITY OF ILLINOIS  
AT CHICAGO MEDICINE

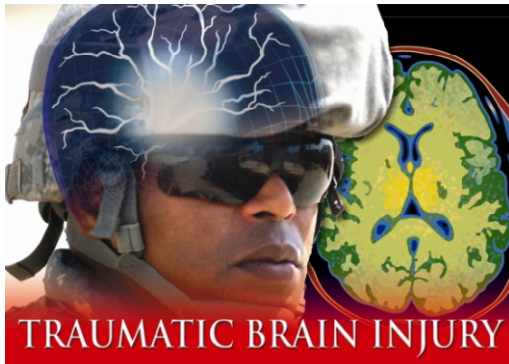




THE UNIVERSITY OF  
CHICAGO

**UIC** COLLEGE OF  
UNIVERSITY OF ILLINOIS  
AT CHICAGO MEDICINE

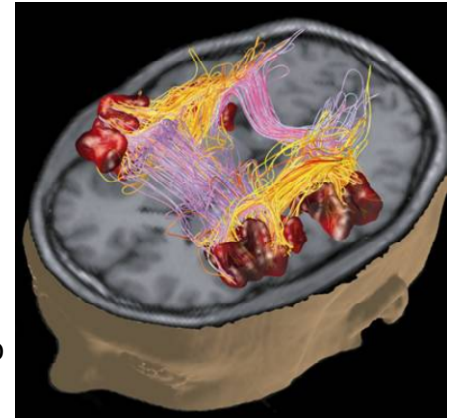
# Diffusion MRI for Traumatic Brain Injury Roadmap Development Workshop



Omni Hotel, Chicago  
2-3 June 2010

University of Chicago  
and  
University of Illinois at Chicago  
and  
Computation Institute

University of Chicago-Argonne National Laboratory



Sponsored by the United States Army  
Telemedicine and Advanced Technology Research Command (TATRC)

This workshop seeks to identify and remove barriers to rapid translation of advanced diffusion MRI technology for evaluation of traumatic brain injury. Standardization and automatization of data acquisition, post-processing and visualization are required for clinical applications. The motivation is the critical and immediate need for better diagnosis and improved treatment of traumatic brain injury in military personnel and veterans. The workshop was organized to promote diffusion MRI technology development in harmony with other TATRC D-MRI project teams around the country. An additional goal is to bring together divergent disciplines and expertise to ensure rapid progress.

The most important product of this planning workshop is development of a roadmap for translation of D-MRI applied to TBI.

- a. Establish an international agenda for advancing the field of DMRI for TBI
- b. Provide a forum to promote and present advancements in the field.
- c. Provide an environment in which participants can network, and identify opportunities for development of collaborations.



# **Table of Contents**

**Meeting Overview and Purpose**

**Meeting Agenda**

**Wednesday, 2 June 2010**

**Thursday, 3 June 2010**

**Invited Participants**

**Corresponding Delegates**

**Workshop Organizers**

**Local Committee**

**Overview Slides for Breakout Groups**

**Breakout Group Assignments**

**Breakout Group Discussion Schedule**

# **Diffusion MRI of Traumatic Brain Injury Roadmap Workshop**

## **Meeting Overview and Purpose**

Diffusion MRI has detected abnormalities associated with brain trauma in many single center studies, but has not yet met the requirements of an imaging biomarker which can support clinical decision making. Despite its potential and widespread availability, diffusion MRI applied to traumatic brain injury has been used only infrequently outside of the laboratory. The reasons are many and include: 1) lack of standardization & quality control for image acquisition, 2) difficulty in extracting quantitative measures of disease presence and burden, 3) limited ability to interpret the results due to insufficient reference data and norms.

Based on current trends, it could take many years before the benefits of diffusion MRI can reach those who need it most, especially injured soldiers and veterans.

A major effort has been made by the TBI and imaging community to review and plan for future work in brain imaging applied to trauma, with several workshops and colloquia resulting in significant progress.

However, there are important unaddressed issues in MRI physics, applied mathematics and computer science, and clinical trials infrastructure needed to optimally acquire, process, and interpret diffusion MRI scans so they can meet the demands of clinical decision making.

With support from US AMRMC through TATRC, a Diffusion MRI of Traumatic Brain Injury Roadmap workshop will be held in Chicago on 2-3 June 2010 to review the recommendations, progress and opportunities from prior workshops, and to plan specific steps needed to translate laboratory methods into clinical practice. The process involves several unique and important aspects: 1) this is the first opportunity for world-leading authorities in diffusion MRI physics and data acquisition, applied mathematics and computer science devoted to analysis of diffusion MRI scans, and traumatic brain injury clinical management experts to meet, 2) the requirements defined by clinical experts can be delivered directly to those who develop the tools needed to conduct and evaluate examinations, and 3) the boundaries between individual institutions, scanner manufacturers, and government agencies which impair data sharing and standardization will be addressed.

The roadmap workshop is a collaborative effort of individuals at the University of Chicago, University of Illinois at Chicago, and the Computation Institute (University of Chicago - Argonne National Laboratory). Institutional representatives with expertise in traumatic brain injury and diffusion MRI neuroimaging from the Chicago area are engaged in the workshop, including the Illinois Institute of Technology, Rush University, Northshore University HealthSystem, Northwestern University, Loyola University, DePaul University, and Purdue University - Calumet.

The participants in this meeting include experts from academia, industry, government agencies (DoD, NIH, VA, NIST, FDA), and several European nations (France, Belgium, The Netherlands, and Germany).

The invited experts include world-leading authorities and pioneers in diffusion MRI physics, applied mathematics, image processing, visualization & analysis, and most importantly, traumatic brain injury.

The schedule includes plenary sessions (8 AM - 3:30 PM on 2 June, 10 AM - 4 PM on 3 June) that are open to the public. Breakout sessions for the expert participants are closed and by invitation only. The group's recommendations will be presented after lunch on 3 June 2010 and include panel discussions.

**Wednesday, June 02, 2010**

**Breakfast**  
**[7 AM – For all workshop participants]**

**Defining the Problem [8AM]**

A unified science of concussion

Jamshid Ghajar MD, PhD, FACS  
[jam@ghajar.net]

DAI and TAI: What are they?

Thomas A. Gennarelli, M.D., FACS

Diffusion MRI and Diffuse Axonal Injury:  
Seeing is not believing

Douglas H. Smith  
[smithdou@mail.med.upenn.edu]

Diffusion Tensor Imaging of Mild Traumatic  
Brain Injury: A Potential Biomarker of  
Neurocognitive Outcome?

Pratik Mukherjee  
[pratik@radiology.ucsf.edu]

Relating diffusion MRI parameters to  
cognition

Anderson, Adam W  
[adam.anderson@Vanderbilt.Edu]

Morphological aberrations in substance  
abuse: Challenges for TBI diagnosis

Bjork, James (NIH/NIDA) [E]  
[bjork@mail.nih.gov]

Diffusion Tensor Imaging: Rewards and  
Pitfalls

Narayana, Ponnada A  
[ponnada.a.narayana@uth.tmc.edu]

DTI Findings in Children Following  
Traumatic Brain Injury: A Developmental  
Perspective

Harvey Levin, Ph.D.

Single subject DTI assessments in blast-  
related TBI: charting a pathway towards  
clinical applications

Christine Mac Donald  
[c\_mac\_donald@yahoo.com]

**Break [10 AM]**

**Experience in Neuroimaging Translation to Clinical Use (stroke, cancer, Alzheimers)**

[10:30 AM]

Imaging biomarkers (NCI - NIST - FDA - etc)

Clarke, Laurence (NIH/NCI) [E]  
[lclarke@mail.nih.gov]

Quantitative diffusion MRI and analysis for early therapeutic change detection applicable in a multi-institutional setting

C R Meyer

BIRN and the Grid - Informatics for neuroimaging

Ian Foster

We've got the solution, so what's your problem: roadblocks to clinical use of diffusion MRI

David Laidlaw [dhl@cs.brown.edu]

Global and voxel-wise analysis of DTI using FA in TBI

Randall Benson, MD

**The Challenge for Translating D-MRI to Clinical Reality**

[11:30 AM]

Standardization of clinical data collection

Andrew Maas, MD

Performing diffusion MRI studies in a multi-center setting: experimental design, artifact remediation, and data processing.

Carlo Pierpaoli [cp1a@nih.gov]

Longitudinal study of D-MRI in TBI - Concept

John Whyte [jwhyte@einstein.edu]

Lunch  
Lunch  
Lunch  
Lunch

[Noon – 1 PM]

## **D-MRI Data Acquisition Physics & Engineering**

[1 PM]

Strategies for DTI Data Acquisition

Roland Bammer  
[rbammer@stanford.edu]

Methodology to Detect and Quantify Injured Regions and Affected Brain Pathways in TBI

Manbir Singh [msingh@usc.edu]

DTI processing using Riemannian frameworks

Xavier Pennec  
[Xavier.Pennec@sophia.inria.fr]

MR Phantoms for Quantification of Brain Imaging

Moreland, John M.  
[john.moreland@nist.gov]

Tips and tricks for assessing diffusion MR data quality

Alexander Leemans  
[Alexander@isi.uu.nl]

Atlas-based anatomical quantification for MRI and DTI

Susumu Mori

Strategies for DWI Analysis: Pros and Cons

Andy Alexander  
[alalexander2@wisc.edu]

TBA - ACRIN/RTOG advanced neuroimaging multicenter clinical trials

Greg Sorensen



**PLENARY SESSION CONCLUDES**

**Break**

**[3:15 PM]**

Group Discussions

Group Discussions

Group Discussions

Group Discussions

Group Discussions

**CONCLUDE DAY 1 DISCUSSIONS**

**[5:15 PM]**

**Thursday, June 03, 2010**

Breakfast – For invited delegates [7:00 AM]

**CLOSED SESSION – BY INVITATION**

**[8:00 AM]**

Group Discussions

Group Discussions

Group Discussions

Group Discussions

Group Discussions

Group Discussions

Group Discussions

Break - BREAKOUT SESSIONS CONCLUDE  
[9:45 AM]

**PLENARY SESSION**

**DoD Perspective - D-MRI of TBI [10 AM]**

Explosive Blast TBI: challenges for MRI

COL Geoffrey S. F. Ling, MD, PhD  
(D Moore will present)

A Military Medicine Perspective on Traumatic  
Brain Injury utilizing DTI

David F. Moore, MD, PhD  
[mooredf@mac.com]

Development of a Comprehensive MRI Protocol  
for TBI in the Military

Gerard Riedy, MD, PhD

## Methods & Applications - D-MRI of TBI

[10:40 AM]

Clinical and neuroscience applications of high-field diffusion MRI

Christophe Lenglet [clenglet@umn.edu]

Axonal beading and its effect on diffusion MRI parameters

Peter Van Zijl

DTI voxel based analysis

Andy Alexander  
[alalexander2@wisc.edu]

High Order Models in Diffusion MRI

Rachid Deriche

What will diffusion MRI tell us about clinical outcomes: The WHO International Classification Framework

Mary Kennedy

DTI of controlled or longitudinal mTBI subjects: how reliable are the results

Zhong, Jianhui  
[Jianhui\_Zhong@URMC.Rochester.edu]

Lunch - [Noon – 1 PM]

Lunch

Lunch

Lunch

**Breakout Group Reports [1:15 PM]**

Plenary - Group 1

[1:45PM] Panel Discussion

Plenary - Group 2

[2:15 PM] Panel Discussion

Plenary - Group 3

[3:00 PM] Panel Discussion

**Workshop Conclusion [3:30 PM]**

Summation; Next Steps

Q&A

**ADJOURN [3:45 PM]**

## **ATTENDEES – DMRI of TBI Workshop (2-3 June 2010)**

Andrew L. Alexander, Ph.D.  
Co-Director, Brain Imaging Core  
Associate Professor of Medical Physics & Psychiatry  
Director of MR Physics Research, Waisman Laboratory, University of Wisconsin

Adam W. Anderson, Ph.D. Associate Professor of Biomedical Engineering  
Associate Professor of Radiology & Radiological Sciences  
Vanderbilt University

Roland Bammer, Ph.D. Assistant Professor of Radiology  
Stanford University

James Beckett VP Clinical Research  
Philips Healthcare, Bothell, WA

Randall R. Benson, M.D. Assistant Professor of Neurology  
Co-Director, Traumatic Brain Injury Imaging Program  
Wayne State University School of Medicine

James Bjork, Ph.D.  
Program Director - Neuroimaging & Neuroeconomics  
National Institute of Drug Abuse  
National Institutes of Health (NIH)

Hal Cecil Charles, Ph.D.  
Co-Director, Center for Advanced Magnetic Resonance Development  
Associate Professor of Radiology; Duke University

Laurence (Larry) Clarke, Ph.D. Branch Chief  
Imaging Technology Development Branch  
NIH/National Cancer Institute

Rachid Deriche, Ph.D. ATHENA Team Leader  
INRIA, Sophia-Antipolis  
France

M. Alex Dresner, Ph.D.  
MR Clinical Scientist, Philips HealthCare, Inc.  
Philadelphia, PA

James C. Gee, PhD Associate Professor of Radiologic Science in Radiology  
Director, Penn Image Computing and Science Laboratory  
Co-Director, Translational Biomedical Imaging Center  
University of Pennsylvania

Thomas A. Gennarelli, MD Chairman of Neurosurgery  
Professor of Neurosurgery; Medical College of Wisconsin

Jamshid Ghajar MD, PhD, FACS President, Brain Trauma Foundation  
Chief of Neurosurgery, The Jamaica Hospital-Cornell Trauma Center

Stuart Hoffman, PhD  
Scientific Program Manager for Brain Injury  
U.S. Department of Veterans Affairs (122)

Jill V. Hunter M.B. B. S., M.R.C.P (U.K.), F.R.C.R.  
Professor of Radiology  
Baylor College of Medicine

David H. Keeler  
Marine Corps Systems Command  
Systems Engineer  
Stafford, VA 22556

Mary R.T. Kennedy, PhD, CCC Associate Professor  
University of Minnesota

David H. Laidlaw, Ph.D.	Professor of Computer Science Brown University	Andrew I.R. Maas, M.D., Ph.D.	Professor & Chairman Department of Neurosurgery University Hospital Antwerp
Alexander Leemans, Ph.D.	Image Sciences Institute University Medical Center Utrecht	Christine L. Mac Donald, PhD;	Postdoctoral Research Scholar Washington University School of Medicine
Heinz U. Lemke, PhD	International Foundation for CARS Technical University of Berlin	Donald Marion, MD, MSc	Deputy Director, Clinical & Educational Affairs Defense and Veterans Brain Injury Center (DVBIC) Walter Reed Army Medical Center
Institute of Advanced Studies University of Munich	Research Professor of Radiology University of Southern California, Los Angeles	Thomas W. McAllister, MD	Millenial Professor of Psychiatry Director of the Section of Neuropsychiatry Dartmouth-Hitchcock Medical Center
Christophe Lenglet, Ph.D.	Research Associate in Radiology & Electrical and Computer Engineering; University of Minnesota	Charles R. Meyer, Ph.D.	Professor - Department of Radiology Professor - Biomedical Engineering; University of Michigan
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Chunlei Liu, Ph.D.	Assistant Professor of Radiology (Medical Physics) Duke-UNC Brain Imaging and Analysis Center Duke University	Susumu Mori, M.S., Ph.D.	Professor, Department of Radiology Johns Hopkins University
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Professor and Vice-Chair of Neurology  
Uniformed Services University of the Health Sciences

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Department of Psychiatry –BO VAMC  
Harvard Medical School  
Boston, MA

Max Wintermark, M.D. Associate Professor  
Neuroradiology Division Chief; University of Virginia





**Andrew L. Alexander, Ph.D.**

My research is focused on the development and application of quantitative MRI methods for characterizing brain tissues and neuropathology. In particular, my lab has focused heavily on the development, application and characterization of diffusion-weighted imaging methods. I am also interested in mapping and characterizing the functional and structural organization of the human brain. These techniques are being applied to study brain changes through the lifespan, developmental disorders like autism, and neurological disorders like multiple sclerosis, Parkinson's disease, and Alzheimer's disease.

1. Lee JE, Chung MK, Lazar M, DuBray MB, Kim J, Bigler ED, Lainhart JE, Alexander AL. (2009) [A study of diffusion tensor imaging by tissue-specific, smoothing-compensated voxel-based analysis](#). *Neuroimage*. Feb 1;44(3):870-83.
2. Jung Y, Samsonov AA, Block WF, Lazar M, Lu A, Liu J, Alexander AL. (2009) [3D diffusion tensor MRI with isotropic resolution using a steady-state radial acquisition](#). *Journal of Magnetic Resonance Imaging*. May;29(5):1175-84.
3. Bendlin BB, Ries ML, Lazar M, Alexander AL, Dempsey RJ, Rowley HA, Sherman JE, Johnson SC. (2008) [Longitudinal changes in patients with traumatic brain injury assessed with diffusion-tensor and volumetric imaging](#). *Neuroimage*. 2008 Aug 15;42(2):503-14.
4. Wu YC, Field AS, Alexander AL. (2008) [Computation of diffusion function measures in q-space using magnetic resonance hybrid diffusion imaging](#). *IEEE Transactions on Medical Imaging*. Jun;27(6):858-65.

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**Adam Anderson, Ph.D.**

Dr. Anderson's research interests are neuroimaging with diffusion MRI and ultra-high field (7T) human MRI. His research projects include histological validation of diffusion tensor imaging (DTI), development of more general mathematical models relating the diffusion MRI signal to tissue microstructure, and applications to specific clinical disorders to improve our understanding of the relations between patient symptoms and biophysical properties of brain tissue. He also works with a group at Vanderbilt to develop human imaging applications, especially high spatial resolution neuroimaging, at 7T.

**Education:**

Ph.D. Physics, 1990, Yale University, New Haven, CT.  
M.Phil. Physics, 1986, Yale University, New Haven, CT.  
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**Roland Bammer, Ph.D.**

**Recent Publications:**

- 
- [Breathheld autocalibrated phase-contrast imaging](#). Lew C, Alley MT, Spielman DM, Bammer R, Chan FP. J Magn Reson Imaging. 2010; 31 (4): 1004-14
  - [Effects of motion and b-matrix correction for high resolution DTI with short-axis PROPELLER-EPI](#). Aksoy M, Skare S, Holdsworth S, Bammer R. NMR Biomed. 2010
  - Yeatman JD, Ben-Shachar M, Bammer R, Feldman HM. Using diffusion tensor imaging and fiber tracking to characterize diffuse perinatal white matter injury: a case report. J Child Neurol. 2009 Jul;24(7):795-800.
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Randall Reed Benson, MD

Randall R. Benson, M.D., an assistant professor of the Department of Neurology at Wayne State University School of Medicine, provided testimony during a Jan. 4 hearing conducted by the House Judiciary Committee in the School of Medicine's Margherio Family Conference Center. The hearing, chaired by U.S. Rep. John Conyers (D-Detroit), included U.S. Rep. Steve Cohen (D-Tenn.) and U.S. Rep. Linda Sanchez (D-Calif.).

"If we're going to get to the bottom of these issues, we need to do a large-scale imaging study to follow NFL players throughout their careers, charting concussions," said Dr. Benson, who is conducting two research projects involving brain imaging of former NFL players.

Specializing in research and clinical treatment of traumatic brain injury, Dr. Benson has spearheaded the use of new imaging techniques, including functional magnetic resonance imaging and susceptible weighted imaging to determine the extent of such injuries. He and an interdisciplinary team of clinicians and researchers are studying impact and non-impact (such as blast exposure) head injuries. Dr. Benson, who stressed the need for the use of more in-depth imaging techniques, showed a variety of images from his research, including one that demonstrated surprising brain movement within the cranium with the simple turning of the head. "There is brain movement occurring with moderate head movement," he said. This could indicate the severe forces and impacts endured by football players at all levels cause concussion and traumatic brain injury.

Dr. Benson noted that even after concussion symptoms diminish, the brain may not have recovered completely. The lack of symptoms of concussion – such as mental confusion or blurred vision -- may not provide an accurate guide for allowing players to resume play. Patients who suffer traumatic brain injury, Dr. Benson told the committee, are frequently misdiagnosed with psychiatric problems. With the symptoms of TBI and psychiatric issues sometimes overlapping, and with the varying degrees of concussion, he said the only objective manner to determine brain injuries is through in-depth imaging.

Randall R. Benson, MD is the only fellowship trained behavioral neurologist at DMC. He has been on the faculty at DMC and WSU since 2001 and is an active member of the teaching faculty, instructing medical students and residents in disorders of cognition and the use of neuroimaging in clinical practice and research.

After a neurology residency at the Boston University School of Medicine and the Boston VA Medical Center (Jamaica Plain), he completed a dual fellowship in cognitive/behavioral neurology and functional neuroimaging at the Massachusetts General Hospital and the MGH NMR-Center

where he pioneered the use of functional MRI (fMRI) for the mapping of language and motor cortex in brain tumor and epilepsy patients. Recruited to the University of Connecticut Health Center in 1997 to direct a new functional imaging program, he teamed with internationally recognized researchers in reading and speech perception and the prestigious Haskins Laboratories in New Haven, CT to investigate the neural (brain) basis of speech recognition using fMRI. With the long-term goal of combining new brain mapping techniques such as fMRI with brain stimulation techniques to effect recovery in brain injured patients, Dr. Benson joined the faculty at WSU/DMC in 2001, where he has used fMRI, together with transcranial magnetic stimulation (TMS) and electrical stimulation, to induce recovery of function in language and motor impaired stroke victims. In work funded by both the Dana and Wilson Foundations, Dr. Benson showed that focal TMS can improve language function in aphasia. In a separate study of hemiparetic stroke, Dr. Benson and colleagues at DMC/WSU showed that electrical stimulation of motor cortex can improve hand motor function.

A newer research and clinical interest for Dr. Benson is traumatic brain injury (TBI). Since coming to WSU/DMC, where there is a rich history of research and clinical management of TBI, Dr. Benson has spearheaded the use of new MRI techniques (e.g., DTI, SWI, PWI, MRSI, fMRI) to brain trauma which is often occult to clinical imaging. Dr. Benson and a large interdisciplinary team of clinicians and researchers (BLAST Consortium) are now fully engaged in studying both impact (NIH funded) and non-impact (blast) head injury, seeking to understand the biomechanical mechanisms, treatment and prevention of injuries.

His research interests include disorders of brain and behavior, including stroke, memory disorders, traumatic brain injury, dementia, adult ADD/ADHD, language disorders and other difficult to diagnose affections of the central nervous system. His research interests are focused on the use of newer functional and structural imaging (e.g., MRI, PET) and brain stimulation methods for diagnosis and treatment of brain injury.

**EDUCATION:**

Undergraduate - Washington University in St. Louis, BA, 1982

Medical - Hahnemann University, MD, 1987

Residency - Boston University School of Medicine, Boston, MA, 1988-1991

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<http://prognosis.med.wayne.edu/article/som-neurologist-recommends-indepth-imaging-study-for-concussions-in-football>

<http://wsupg.med.wayne.edu/view.php?id=D0NF0SBZEC>

<http://neurology.med.wayne.edu/behavioral-alzheimers/profile.php?id=1844>



**James M. Bjork, Ph.D.**

Dr. Bjork is NIDA's point-person on the intersection between traumatic brain injury and drug abuse. He also handles grants and applications proposing to use dynamic or structural measures of connectivity in drug abusers, or pertaining to processes germane to drug abuse or impulsivity. His research encapsulates what key topics of interest to NIDA concerning TBI and drug abuse.

In addition, he has served in a liaison role with the DoD in their Defense Centers of Excellence

<http://www.dcoe.health.mil/>

project to define "Common Data Elements" for drug use and abuse in health surveillance of soldiers.

<http://www.dcoe.health.mil/blog/article.aspx?id=1&postid=30>

<http://www.commondataelements.ninds.nih.gov/TBI.aspx>

<http://www.tbi-impact.org/cde/>

and his workgroup leader was Dan Kivlahan at the Seattle VA.

One of Dr. Bjork's grantees, Pilou Bazin at Johns Hopkins, has a NIDA grant to develop and distribute software for quantifying brain volumes with precise reference to brain atlases. Pilou has now added a module for white matter lesion characterization (using MS patients).

Here's a link to the distribution web-site:

<http://www.nitrc.org/projects/toads-cruise/>

<http://medic.rad.jhmi.edu/>

## **Traumatic Brain Injury is an Understudied Risk Factor for Drug Abuse**

A large body of research has established that drug and alcohol use are risk factors for traumatic brain injury (TBI). In contrast, whether TBI increases the risk of substance abuse in people who were not abusing drugs before experiencing a TBI is unclear. With the number of TBI survivors in the United States increasing dramatically due to the wars in Afghanistan and Iraq, more research in this field is urgently needed, explain NIDA investigators in a recent review article. Many challenges to studying the link between TBI and substance abuse exist, including the fact that a diagnosis of TBI includes a wide range of injury types, many of which are difficult to detect even with modern imaging techniques. Some preliminary studies have indicated that TBI may increase drug or alcohol use in people without a history of substance use or dependence. For example, in a study of about two million military personnel, those with a mild TBI were more than two and a half times likely to be discharged from the military due to alcoholism or drug use. Individuals with a moderate TBI were over five times as likely. Animal studies suggest that TBI may disrupt brain dopamine pathways (these pathways mediate the effects of all drugs of abuse), however experiments directly examining drug-related behavior after TBI have not been performed. The authors state that both laboratory and clinical studies are needed to understand whether TBI alone can increase the risk of drug abuse in the absence of other risk factors, and to measure the extent to which TBI increases drug abuse or triggers relapse in people with a history of substance abuse.

Bjork JM, Grant SJ. Does traumatic brain injury increase risk for substance abuse? *J Neurotrauma*. 2009 Feb 9.

The research investigators, Drs. Steve Grant and James Bjork, are extramural program officials in NIDA's Division of Clinical Neuroscience and Behavioral Research.

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**Hal Cecil Charles, Ph.D.**

Dr. Charles is an Associate Professor of Radiology, a chemist and an expert in MR imaging and spectroscopy with over 25 years of experience in nuclear magnetic resonance. He serves as the Co-Director of the Duke Center for Advanced Magnetic Resonance Development. He also has extensive experience in conducting imaging and spectroscopy studies. He has had extensive experience in conducting longitudinal clinical trials with MRI and MRS used as imaging biomarkers. He is also director of the Duke Image Analysis Laboratory which is active in conducting clinical trials in CNS disorders (schizophrenia, MCI, AD), cancer, and osteoarthritis using imaging biomarkers. His lab recently initiated a new project in imaging lung ventilation in humans with 19F MRI.

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**Laurence P. Clarke, Ph.D.**

Dr. Clarke is the Branch Chief for Imaging Technology Development Branch, Cancer Imaging Program (CIP), Division of Cancer Treatment and Diagnosis, [National Cancer Institute at NIH](#). In this capacity, he is responsible for the development of research strategies and initiatives for supporting new and emerging imaging technologies and methods that support both academia and industry communities to address the cancer problem. His responsibilities include the development of web assessable research resources for benchmarking the performance of new and emerging imaging platforms and clinical decision tools. Dr. Clarke oversees several research networks for the development of quantitative imaging methods for current and the next generation of imaging platforms and methods as required for future multi center clinical trials.

Dr. Clarke has a detail assignment with National Institute of Bioengineering (NIBIB) and guest scientist at the National Institute of Standards and Technology, where his responsibility is to encourage performance standards for informatics and related clinical decision tools as applied to medical imaging.

Before joining NCI, Dr Clarke was a Professor of Radiology and Physics at the University of South Florida (USF), and a Program Leader for Digital Medical Imaging Program. He was also a full member of the NCI designated H. Lee Moffitt Cancer and Research Center at USF. He has previously worked at other cancers centers including University of Miami, Florida, and the Memorial Sloan Kettering Cancer Center, NY, NY. Dr. Clarke has been active in academia over the last 30 years in the area of medical physics and image processing for early cancer detection, cancer diagnosis and treatment. He is a Research Fellow of the ISMRM and AAPM. He graduated with a PhD in physics at the National University of Ireland (1978) and an MS degree from Queens University of Belfast, Ireland (1968).

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**Rachid Deriche, Ph.D.**

I am Research Director at [INRIA](#) in the [Sophia Antipolis - Mediterranee Research Center](#) where I lead the team [ATHENA](#) focused on the Computational Imaging of the Central Nervous System. I am also teaching graduate courses on Biomedical Imaging, Computer Vision and Image processing in the following Master of Sciences 2 : [Master of Science in Computational Biology](#) and [Parisian Master of Research in Computer Science](#) and in the following engineering school [Telecom Sud Paris](#).

I am member of the INRIA Sophia Antipolis - Mediterranee Management board, vice-chair of the INRIA Sophia project-team committee (Since Sept. 1st, 2008), member of the INRIA Evaluation Committee and vice-Director of the [STIC Doctoral School](#).

I am Associate Editor of [SIAM Journal on on Imaging Sciences \(SIIMS\)](#), member of the editorial board of [Computational Imaging and Vision book series](#) and currently Co-chair of [ICPR 2010 : Track VI: Bioinformatics and Biomedical Applications](#). I have been Associate Editor for many years for journals such as [IJCV](#) and area-chair for many conferences such as ECCV, ICCV, CVPR, MICCAI, RFIA, ISBI etc

**Research Interest:** My expertise and research interests are in Computational Imaging of the Central Nervous System (CNS - Brain and Spinal Cord), 3D Computer Vision and Mathematical Image Processing. More recently, i shifted my research interest from the domain of 3D Computer Vision to the domain of Computational CNS Imaging with a particular emphasis on the understanding and the processing of the CNS anatomical connectivity through Diffusion MRI and its combination with other modalities such as fMRI, MEG or EEG. More generally, i am very interested by the development and application of mathematical and computational imaging methods to help understand how the brain works and acquire a better understanding of its mechanisms.

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**M. Alex Dresner, Ph.D.**

I'm a Philips MR Clinical Scientist, so I focus on the research that a particular site wants to perform; my home site is Thomas Jefferson University in Philadelphia and we have projects on body and musculoskeletal research, as well as investigating spinal cord injury with DTI. I also partner with two sites in New York City using MR to study TBI and look forward to sharing the workshop information with them. The role of the clinical scientist is to harvest the most promising academic research for the MR system developers, in order to improve the ability of clinicians to diagnose and monitor disease.

Before working for Philips, I did postdoctoral research in fMRI at Hammersmith Hospital with Imperial College London, and prior to that performed my Ph.D. research in MR elastography at Mayo Graduate School in Minnesota.

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**James C. Gee, Ph.D.**

Dr. Gee's major area of interest is biomedical image analysis and computing, with active research in all of the quantitative methods represented, including segmentation, registration, morphometry and shape statistics, as applied to a variety of organ systems and all of the major and emerging modalities in biological/biomaterials imaging and in vivo medical imaging.

**Education:**

B.S. (Electrical Engineering), University of Washington, 1987.  
B.S. (Computer Science), University of Washington, 1987.  
M.S. (Electrical Engineering), University of Washington, 1989.  
Ph.D. (Computer and Information Science), University of Pennsylvania, 1996.

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### **Thomas Gennarelli, MD**

Dr. Thomas Gennarelli, an internationally renowned clinician and researcher in the field of traumatic head injuries, was appointed to the faculty at the Medical College of Wisconsin as a professor in 1999 and fulfilled the administrative duties as chairman of the Department during 1999-2008.

Thomas A. Gennarelli was born in Berwyn, Illinois, ancestral home of two other neurosurgeons, John Jane and Tony Raimondi, on the birth date of his subsequent first chairman, Tom Langfitt (April 20). After meeting his future wife, Kay at Northwestern University, he rotated through Raimondi's service at Cook County Hospital during a junior clerkship at Loyola University medical School. It was here his first neurosurgical interest was spawned further solidified after 1968 medical school graduation by encounters as a surgical intern at Rush-Presbyterian St. Lukes University Hospital, on the service of Dr. Walter Whisler and Dr. Eric Oldberg.

He went to Boston for a fellowship in neurology and because of an early interest in pediatric neurosurgery, divided time between the Brigham and the Children's Hospital, emphasizing seizure studies, EEG's and neurophysiology in the Seizure Unit of Dr. Cesare Lombroso at Children's.

From 1970 to 1972, the Viet Nam conflict demanded military service. He was appointed to the Public Health Service and went to Bethesda, stationed at the NIH. Gennarelli worked with Dr. John Van Buren and Dr. Ayub Ommaya in the Surgical Neurology Branch and there began a persisting interest in CNS injury while working in Ommaya's laboratory. At the end of the two-year stay in the PHS, Gennarelli was making progress in the brain injury laboratory and decided to stay in the Washington area for residency training. Dr. Al Luessenhop agreed to take him on as a neurosurgery resident at Georgetown University from 1972-1976.

Tom Langfitt, then chairman of neurosurgery at the University of Pennsylvania, offered Gennarelli a position as Assistant Professor, Director of Experimental Head Injury and Director of the Neurosurgical Intensive Care Unit. These titles, in lieu of high salary, were too attractive to pass up, so he moved to Philadelphia in 1976.

He remained there until 1995 rising through the academic ranks to Professor, Vice Chair and Director of the Head Injury Center. His primary focus in neurotrauma was augmented by a clinical interest in surgery of the parasellar regions. In 1995, he moved across town to the chair the Department of Neurosurgery in the new Medical School that resulted from the merger of the Medical College of Pennsylvania and Hahneman University. He remained there for four years,

until the school, which was renamed Allegheny University of the Medical Sciences, had serious financial woes. Learning all he cared to about bankruptcy, in 1999 Dr. Gennarelli moved back to the Midwest to take over the Chair of the Department of Neurosurgery from Sam Larson who was retiring from the Medical College of Wisconsin in Milwaukee.

Board certified in neurological surgery and advanced trauma life support, Dr. Gennarelli has served as president of the International Neurotrauma Society, on the board of directors of the Coalition for American Trauma Care and is past president of the Association for the Advancement of Automotive Medicine (AAAM). He is also a founding member of the International Neurotrauma Society, the International Society for Neuroemergencies and the Eastern Association for the Surgery of Trauma. He is a Fellow of the American College of Surgeons, AAAM and the American Association for the Surgery of Trauma.

Dr. Gennarelli founded The Froedtert Hospital & The Medical College of Wisconsin CIREN Center, the tenth center of the Crash Injury Research and Engineering Network (CIREN) of the National Highway Traffic Safety Administration, US Department of Transportation. He has published 406 original research papers, written 41 book chapters and four editions of "The Abbreviated Injury Scale," the international standard for determining the severity of bodily injuries. He has served as an editorial advisor for a dozen peer-reviewed journals, a consultant or special advisor to 20 major injury prevention programs, and a visiting professor to over 50 universities in the United States and abroad.

Among his honors are membership in Alpha Omega Alpha, the national medical honor society, and Alpha Sigma Nu, the national Jesuit honor society. Dr. Gennarelli has received the National Head Injury Foundation's 1984 Caveness Award for outstanding contribution to head injury, the Association of Advancement of Automotive Medicine's 1988 A.J. Mirkin Service Award, and its 1990 Award of Merit for contributions to brain injury research, and its 1991 award for best scientific paper. He received the NINDS's 1991 Brain Injury Research Award. He has been named by his peers as a "Best Doctor in America" from 1984-2011 and to "Who's Who in America" and "Who's Who in the World."

Dr. Gennarelli received his medical degree with honors from Loyola University Stritch School of Medicine in Chicago. He completed a residency in neurological surgery at Georgetown University Hospitals, a neurology fellowship at Harvard Medicine School and a surgery internship at Rush-Presbyterian-St. Luke's Medicine Center in Chicago.

In addition to his expertise in brain injury, Dr. Gennarelli has specialized in surgical treatment of brain tumors, pituitary tumors, visual disorders, vascular diseases of the brain and facial pain. He has been especially interested in minimally invasive surgery and skull base surgery.

***Professor of Neurosurgery***

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### **Jamshid Ghajar, MD, PhD, FACS**

Dr. Jamshid Ghajar completed the MD/PhD program at Cornell University Medical College, with a PhD dissertation on brain chemistry and metabolism during coma.

After completing his residency training in neurosurgery at New York Presbyterian Hospital, he joined the faculty and founded the Brain Trauma Foundation. The mission of the Brain Trauma Foundation (BTF) is to improve the outcome of patients with traumatic brain injury (TBI).

He is the principal investigator on the Department of Defense (DoD) Advanced Technology award to develop a portable and rugged eye tracking diagnostic device for concussion. He is also the principal investigator on the James S. McDonnell Foundation collaborative grant award to study cognitive function and recovery following mild traumatic brain injury.

Dr. Ghajar is Chief of Neurosurgery at Jamaica Hospital-Cornell Trauma Center, Clinical Professor of Neurosurgery at Weill Cornell Medical College and President of the Brain Trauma Foundation.

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**Stuart Hoffman, PhD**

Stuart Hoffman, PhD, is the Scientific Program Manager for the Brain Injury portfolio, which includes traumatic brain injury (TBI) and stroke. Dr. Hoffman received his doctoral degree in behavioral and molecular neuroscience at Rutgers University in 1995 and completed his postdoctoral training in pharmacology at Virginia Commonwealth University's medical campus in 1997. Prior to accepting this position with VA, he was an assistant professor in the Department of Emergency Medicine at Emory University. Dr. Hoffman was also faculty in both the graduate and undergraduate neuroscience programs at Emory University, where he codeveloped and directed a multidisciplinary course on neurotrauma. He was previously the Research Director for the Defense and Veterans Brain Injury Center in Johnstown, Pennsylvania. Dr. Hoffman has more than 24 years of experience and has authored over 45 peer-reviewed publications in translational research on neuroprotection and recovery of function after brain injury.

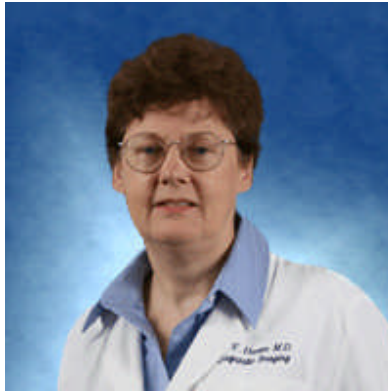
Dr. Hoffman has research experience in the following brain injury areas: in vitro TBI models, animal models of TBI, development of animal rehabilitation models, rodent brain ischemia models, translational drug development for neuroprotection, and clinical neurorehabilitation research.

Developing effective rehabilitation strategies for TBI, the signature injury of the conflicts in Iraq and Afghanistan, is an urgent concern for the nation's Veterans. The VA's Office of Rehabilitation Research and Development (RR&D) is responding to this concern in several ways. First, to ensure that the RR&D TBI research program supports innovative and timely research that complements civilian and military research programs, the VA sponsored State-of-the Art (SOTA) Conference on TBI research to inform research planning. The VA also hosted a meeting of international experts to review the approach to patient care and advise on future research needs. Second, to encourage expanded efforts in TBI research, RR&D recently released an RFA for TBI research based on the recommendations of the SOTA Conference. As a result, there has been an increase in the number of applications for TBI research, including proposals for both Merit Awards and Centers of Excellence. Among the important TBI-related topics of research to be addressed by RR&D funded researchers are basic science to better understand the underlying mechanisms of injury and potential for regeneration and recovery, including from blast injury; development of improved neuroimaging techniques to aid diagnosis and guide effective treatment; and development of evidence-based rehabilitation methods. Research efforts will expand the TBI program and refine it to better respond to the unique needs of Veterans with TBI.

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### **EDUCATION**

#### **FELLOWSHIP ►**

Neuroradiology Fellow: 1988 - 1992  
National Hospital for Neurology and Neurosurgery  
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General Radiology Fellow: 1985 – 1988  
Guy's Hospital, London University  
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Neurology and Research Fellow: 1981 – 1982  
Atkinson Morley's Hospital & Brompton Hospital  
London University, London, England

Internal Medicine Fellow: 1978 – 1981  
Brompton Hospital, King's College Hospital and St. George's Hospital  
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#### **RESIDENCY ►**

Radiology Residency: 1982 – 1985  
St. Thomas' Hospital  
London University  
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Internal Medicine Residency: 1977 – 1978  
King's College Hospital and Whittington Hospital  
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#### **INTERNSHIP ►**

Medicine and Surgery: 1976  
Whipps Cross Hospital and St. Bartholomew's Hospital Rotation  
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#### **MEDICAL SCHOOL ►**

St. Bartholomew's Hospital Medical College: 1970 - 1975  
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**David H. Keeler**

Mr. Keeler is an electrical and biomedical engineer with expertise in medical device development, signal processing, embedded systems, and data acquisition system development. He has previously carried out investigations involving gamma scintigraphy, ventricular fibrillation mapping, microcontroller system control and data acquisition, embedded LabVIEW, and real-time software and hardware development. Mr. Keeler is currently Systems Engineer for the Family of Field Medical Equipment, Combat Support Equipment, Marine Corps Systems Command, Quantico, VA.

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**Mary R.T. Kennedy, Ph.D., CCC**

Mary Kennedy, Ph.D., CCC, is an Associate Professor at the University of Minnesota. With 30 years of experience working with individuals with traumatic brain injury (TBI), she is published widely and has presented nationally and internationally on the cognitive and communication disorders of this population. She is currently chair of Academy of Neurological Communication Disorders & Sciences (ANCDS) committee on practice guidelines for individuals with TBI.

**Reference:** Mary R.T. Kennedy, et al. White matter and neurocognitive changes in adults with chronic traumatic brain injury. *Journal of the International Neuropsychological Society* (2009), 15:130-136.

**Education:**

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**David Laidlaw, Ph.D.**

David Laidlaw is interested in visualization and modeling applications of computer graphics and computer science to other scientific disciplines. Applications give a real-world direction to computational research and are also compelling because they can provide concrete answers to questions about how our world works. He is working with researchers in, for example, archaeology, developmental neurobiology, medical imaging, orthopedics, art, cognitive science, remote sensing, and fluid mechanics to develop new computational applications and to understand their strengths and weaknesses. Some research problems he is particularly interested in are visualization of multivalued multidimensional imaging data, comparisons of virtual and nonvirtual environments for scientific tasks, and applications of art perception and cognition to visualization.

He earned a Computer Science PhD from Caltech while working in the graphics group there. His post-doctoral work, also at Caltech, was in the Fraser lab in the Beckman Institute (a part of the Biology division ).

The work of his group, the Visualization Research Lab (VRL), is described in a set of web pages outlining organizing themes, individual projects, people, and other resources.

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**Alexander Leemans, Ph.D.**

Alexander Leemans graduated in Physics in 2002 and obtained his PhD in 2006 at the Vision Lab (Antwerp University - Belgium) in collaboration with the Bio-Imaging Lab (Antwerp University - Belgium), the University Hospital of Antwerp (Belgium), the Martinos Center (Harvard/MIT - Boston, USA), and the in-vivo NMR center (University of Alberta - Edmonton, Canada). In January 2007, he started a post-doc at the Cardiff University Brain Research Imaging Centre (CUBRIC) - School of Psychology, Cardiff University, United Kingdom. He is currently a faculty member at the Image Sciences Institute - University Medical Center Utrecht, The Netherlands.

My recent and ongoing scientific research focuses on modelling, processing, and analyzing diffusion MRI data for investigating microstructural and architectural properties of living tissue. My main research topics include coregistration for diffusion tensor imaging (DTI) data, construction of diffusion MRI atlases, fiber tractography, fiber clustering, quality assessment of diffusion MRI data, motion and distortion correction, visualization, and high angular resolution diffusion (HARD) MRI processing.

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**Heinz U. Lemke, Ph.D.**

Prof. Dr.-Ing. Heinz U. Lemke, born in 1941, is the Director of the International Foundation for Computer Assisted Radiology and Surgery (CARS). He is Professor of Radiology at the University of Southern California, Los Angeles, and Professor for Computer Assisted Surgery at the Innovation Center Computer Assisted Surgery (ICCAS), University of Leipzig. From 1975 to 2006, he was Professor of Computer Science at Technical University Berlin, where he chaired the Department of Computer Graphics and Computer Assisted Medicine. Prof. Lemke is the editor-in-chief of the International Journal of Computer Assisted Radiology and Surgery (IJCARS). His research interests include the development of medical work stations for computer assisted diagnosis and therapy planning, the analysis of surgical workflow and the development of ICT standards for the digital operating room. He is the author of pioneering works in these areas.

Dr. Lemke is organizer of the Computer Assisted Radiology and Surgery annual meeting. In 2010, this meeting will be held in Geneva, Switzerland. The CARS congress with its associated journal is a facilitator of innovation and an important contributor to modern medicine on a worldwide basis. Founded in 1985, CARS with its focus on research and development for computer assisted systems and their applications in radiology and surgery has played a leading role in medical informatics for 25 years. Its growth and impact is due to CARS's close collaboration with the ISCAS, EuroPACS, CAR, CAD and CMI societies. Following the long term successful cooperation, they will jointly hold their annual meetings with CARS in Geneva in 2010.

- 1966 – 1970 Computer Science studies at the Universities of London and Cambridge
- 1970 doctorate Dr. phil. at Computer Laboratory at the University of Cambridge
- 1974-2006 Professorate for Computer Science (Computer Graphics and Computer Assisted Medicine) at the Technical University of Berlin.
- Co-founder and board member of the “International Society of Computer Aided Surgery” (ISCAS), “World Academy of Biomedical Technology” (WABT) and “German society for computer- and robot assisted surgery”(CURAC)
- He is co-publisher and scientific advisor of numerous professional journals.

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**Christophe Lenglet , Ph.D.**

Christophe Lenglet is a Research Associate in Radiology & Electrical and Computer Engineering at the University of Minnesota. Prior to that, he was a Research Scientist in the Imaging & Visualization department at Siemens Corporate Research (Princeton, NJ). He obtained a Ph.D. in biomedical imaging / neuroscience from INRIA Sophia-Antipolis where he developed mathematical models and computational tools for the analysis of diffusion MRI. He has M.S. degrees in applied mathematics from Ecole Normale Supérieure de Cachan and in computer science and engineering (minor in neuroscience) from Compiègne University of Technology. His research interests include clinical and neuroscience applications of (high field) MRI, neurodegenerative diseases, anatomical and functional connectivity mapping and neuroanatomy.

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**Elizabeth C. Leritz, Ph.D.**

**Elizabeth C. (Betsy) Leritz** is an Instructor in Medicine at Harvard Medical School, an Associate Epidemiologist at Brigham & Women's Hospital Division of Aging, and is an Investigator in the Geriatric Neuropsychology Laboratory at the VA Boston Healthcare System. She received her Ph.D. in Clinical Psychology with specialization in Neuropsychology from the University of Florida in 2004. She completed an internship and post-doctoral fellowship in Geriatric Neuropsychology at the VA Boston Healthcare System.

Dr. Leritz's work focuses on using neuroimaging to understand cognitive changes that accompany aging, age-associated diseases, and brain injury. Her current research, supported by an NINDS Career Development Award, examines how risk factors for age-related cognitive decline and dementia contribute to neural alterations and neuropsychological changes, and how cognitive reserve mediates these relationships. More recently, she has expanded her work to focus on how mild TBI and stress-related disorders impact brain structure and cognition. This work is conducted specifically in OEF/OIF veterans, as part of the newly funded VA Rehabilitation Center of Excellence center called the Translational Research Center for Traumatic Brain Injury and Stress Disorders (TRACTS) at the VA Boston Healthcare System. She is specifically involved in the portion of TRACTS that uses structural and functional imaging techniques to examine the neural and cognitive consequences of mild TBI and post-traumatic stress disorder (PTSD).

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**Harvey S. Levin, Ph.D.**

Dr. Levin leads an NIH supported, two center project concerning neurobehavioral recovery from traumatic brain injury (TBI ) in children. The focus of this study is on development of social cognitive and executive functions in children following TBI, particularly in relation to multimodality brain imaging. In addition, the Laboratory is engaged in a longitudinal, translational NIH supported project on mild TBI which also uses multimodality brain imaging. The Laboratory is engaged in a consortium of investigators studying acute mild TBI in a DOD supported project. Dr. Levin is Director of a Veterans Affairs Center of Excellence on TBI which includes multimodality brain imaging of veterans with mild blast-related TBI.

Dr. Levin's clinical interests include neuropsychological assessment of neurosurgical patients, especially patients undergoing resection for treatment of intractable epilepsy.

He is Director of an NIH-funded T-32 postdoctoral program in mentored rehabilitation research which emphasizes neuroplasticity and neuroimaging.

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**Chunlei Liu, Ph.D.**

Dr. Liu is a core faculty member of the Brain Imaging and Analysis Center (BIAC) of Duke University School of Medicine. His research interest is in advancing magnetic resonance imaging and analysis techniques for translational medical applications. He is developing ultra high-resolution diffusion tensor imaging methods that allow more detailed and more specific visualization of brain connectivity. His recent efforts have resulted in the development of a susceptibility-tensor imaging technique that permits the study of white matter microstructure at high magnetic field strength.

Dr. Liu collaborates closely with Radiologist, Psychologists and Neuroscientists. He is part of a research effort on the application of DTI in traumatic brain injury that is funded by the U.S. Department of Veterans Affairs.

**Education:**

B.S. 1998, Peking University (Physics)

M.S. 2000, University of North Carolina at Chapel Hill (Physics)

M.S. 2003, Stanford University (Management Science and Engineering)

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**Guoying Liu, Ph.D.**

Dr. Guoying Liu is the Program Director of the Magnetic Resonance Imaging (MRI) and Magnetic Resonance Spectroscopy (MRS) programs at NIBIB. Dr. Liu received her Ph.D. in physical chemistry in 1991 from the University of Illinois at Urbana-Champaign, followed by a postdoctoral fellowship at the *in vivo* MR Research Center at NIH. From 1995 through 1997, she was a member of the faculty of Albert Einstein College of Medicine in the Department of Radiology and Department of Neuroscience where her research focused on the development of MR techniques for imaging neuronal activity and connections, and for imaging of diffusion and perfusion in the brain.

From 1997 to 2001, Dr. Liu served as a faculty member at Georgetown University's Institute for Cognitive and Computational Sciences and Department of Neurology. Her research lab continued the work on MR technical development and application with a focus on human auditory signal processing and phonological organization. From 2001 until joining NIBIB in September of 2008, she served as Program Director of the Cancer Imaging Program at the National Cancer Institute. Dr. Liu co-led a number of working groups on DCE-MRI, MRSI, and Diffusion MRI as they apply to cancer and spearheaded the efforts on building consensus by working with the scientific community that lead to the NCI guidelines on the clinical use of these MR methods.

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**Mark J. Lowe, Ph.D.**

**Education & Fellowships**

**Doctorate - University of Minnesota**

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1991

**Undergraduate - Michigan State University**

East Lansing, MI USA  
1986

**Innovations & Patents**

- Integrated System for the Production of MRI Safe Implantable Pacing Devices
- Magnetic Resonance Measurement and Imaging of Currents
- Direct Thermal Monitoring for MRI Safety Intervention
- Determination of Physiologic Noise Sources in MRI Data Using Independent Component Analysis

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**Andrew Maas, MD. PhD.**

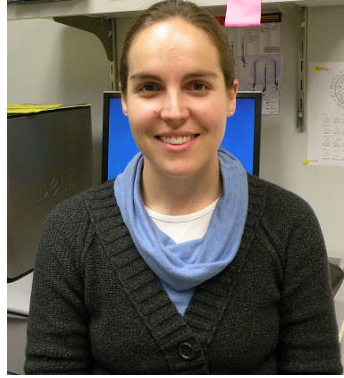
Andrew I.R. Maas, MD, PhD, is Professor and Chairman of Neurosurgery at the University Hospital Antwerp, Belgium. Furthermore he is chairman of the Executive Committee of the European Brain Injury Consortium (EBIC), president of the International Neurotrauma Society and member of the neurotraumatology Committee of the WFNS. He has participated in the development of Evidence Based Guidelines for Management and Prognosis of severe traumatic brain injury ([www.braintrauma.org](http://www.braintrauma.org)) and has substantially contributed to the production of evidence based guidelines for the treatment of penetrating head injury (J. Trauma 2001). He has been actively involved, both as investigator and member of the Executive Committee in many of the studies included in the IMPACT database. He is also Chairman of the European Brain Injury Consortium and a member of the Neurotraumatology Committee of the World Federation of Neurosurgical Societies. His research is mainly in the field of neurotraumatology. Prof. Maas is Principal Investigator of the Impact Project. (<http://www.tbi-impact.org/>)

Maas AI, Marmarou A, Murray GD, Teasdale SG, Steyerberg EW. Prognosis and clinical trial design in traumatic brain injury: the IMPACT study. J Neurotrauma. 2007 Feb;24(2):232-8.

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**Christine L. Mac Donald, Ph.D.**

My research is focused on advanced MR methods for the evaluation of traumatic brain injury both in the civilian and military population. Diffuse axonal injury is thought to be a major contributor to cognitive dysfunction in patients following traumatic brain injury (TBI). However, it is difficult to diagnose anti-mortem, and new diagnostic methods are needed. Current clinical imaging modalities have been optimized to assess haemorrhage and ischemia but are inadequate for the direct assessment of axonal injury. Diffusion tensor imaging (DTI) has shown promise but it has yet to be fully validated for its potential role as a diagnostic tool in the evaluation of brain injury. Resting-state functional MRI (fMRI) correlation analysis has also been proposed as a useful tool in the evaluation of brain functional connectivity (fcMRI). The basis of this method is that anatomically connected regions in the brain show correlated fluctuations in the blood oxygen level dependent (BOLD) signal. Our initial studies indicate that these methods have high clinical utility and could be easily implemented as part of the standard imaging protocol for trauma. This work has given further insight into the structural and functional changes occurring following injury and added additional information not previously apparent from conventional MR imaging. In the future, these techniques may be able to better assist with diagnosis and prognosis as well as stratify patients for therapeutic intervention.

1: MacDonald CL, Schwarze N, Vaishnavi SN, Epstein AA, Snyder AZ, Raichle ME, Shimony JS, Brody DL. Verbal memory deficit following traumatic brain injury: assessment using advanced MRI methods. *Neurology*. 2008 Oct 7;71(15):1199-201.

2: Mac Donald CL, Dikranian K, Bayly P, Holtzman D, Brody D. Diffusion tensor imaging reliably detects experimental traumatic axonal injury and indicates approximate time of injury. *J Neurosci*. 2007 Oct 31;27(44):11869-76.

3: Brody DL, Mac Donald C, Kessens CC, Yuede C, Parsadanian M, Spinner M, Kim E, Schwetye KE, Holtzman DM, Bayly PV. Electromagnetic controlled cortical impact device for precise, graded experimental traumatic brain injury. *J Neurotrauma*. 2007 Apr;24(4):657-73.

4: Mac Donald CL, Dikranian K, Song SK, Bayly PV, Holtzman DM, Brody DL. Detection of traumatic axonal injury with diffusion tensor imaging in a mouse model of traumatic brain injury. *Exp Neurol*. 2007 May;205(1):116-31.

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**Donald Marion, MD, MSc**

Donald Marion, MD, MSc is an academic neurosurgeon who has focused on the clinical pathophysiology and treatment of traumatic brain injury (TBI) for more than 25 years. He was among the charter authors of the Brain Trauma Foundation's Guidelines for the Management of Severe Traumatic Brain Injury. He published the first clinical report to show benefit of therapeutic moderate hypothermia for TBI in 1997 (The New England Journal of Medicine). He is the editor of a book entitled Traumatic Brain Injury, and has authored or co-authored approximately 200 journal articles and book chapters, most related to TBI. Dr Marion's previous positions have included Professor and Chair of the Department of Neurosurgery, The Boston University School of Medicine; Professor and Vice-Chair, Department of Neurosurgery, The University of Pittsburgh School of Medicine; and Director of the Brain Trauma Research Center at the University of Pittsburgh. He is past Chair of the Joint Section on Neurotrauma and Critical Care, the American Association of Neurological Surgeons and Congress of Neurological Surgeons; past President of the National Association of Injury Control and Research Centers; and past Chair of the Neurosurgery Subsection, the Committee on Trauma, American College of Surgeons. Dr Marion sits on the Editorial Boards of Neurosurgery, The Journal of Trauma, and The Journal of Neurocritical Care. He has served as the Science Officer of the Children's Neurobiological Solutions Foundation (CNS), Santa Barbara, CA, and managed the Foundation's stem cell grant portfolio, designed and organized the semiannual young neuroscientists workshops, and contributed to the Foundation's e-newsletter. He also serves as a regular ad hoc member of the Developmental Brain Disorders NIH Study Section.

Dr Marion completed undergraduate studies at St John's University, Collegeville, MN in 1975. He then became a Leprosy Control Worker as a Peace Corps Volunteer in South Korea from 1976-1978. He earned his MD degree from the University of California at San Francisco School of Medicine in 1982, and completed an internship in general surgery, residency in neurosurgery, and a Masters Degree in Neurobiology at the University of Pittsburgh School of Medicine in 1989. From 1989 to 1990 he spent a year at the Medical College of Virginia as a Jacob Javitz Neurotrauma Fellow where he was exposed to clinical and basic science models of neurotrauma research. Following his fellowship he joined the faculty at the University of Pittsburgh School of Medicine where he founded the Brain Trauma Research Center and was Chief of the Neurotrauma Service.

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**Thomas W. McAllister, M.D.**

Thomas W. McAllister, M.D., is the Millennium Professor and Vice-Chair for Neuroscience Research in the Department of Psychiatry at Dartmouth Medical School. He is Director of the Section of Neuropsychiatry and is a past president of the American Neuropsychiatric Association. Dr. McAllister received his undergraduate degree from Dartmouth College, and his medical degree from Dartmouth Medical School. He served on the faculties of the University of Kentucky, and the University of Pennsylvania before returning to Dartmouth Medical School in 1990.

He has a long-standing interest in the neuropsychiatric problems of individuals with traumatic brain injury, and his current research explores catecholaminergic modulation of cognitive deficits following mild and moderate TBI as well as neurobiological effects and genetic predictors of outcome of head injury in athletes.

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**Charles R. Meyer, Ph.D.**

In addition to his own recent work to quantitatively evaluate breast cancer response to neoadjuvant chemotherapy, he has been involved in several projects that have contributed in various ways to collaborative research. The first of these was the Lung Image Database Consortium (LIDC) RFA CA01-001 which funded five U01s over the period 2002-2007. The LIDC product of over 1000 CT datasets each annotated by 4 expert chest radiologists, and 285 associated annotated chest radiographs soon to be released, will provide a large training dataset to a wide background of investigators for CAD algorithm development. He participated in NCI CIP's Reference Image Database to Evaluate Response (RIDER) contract effort following LIDC. This work focused on describing sources of truth data and measurement methods to assess the relative accuracy of algorithms for evaluating early response to therapy. Additionally as part of the RIDER effort his group at Michigan has contributed several short interval breast DW MRI exams, they call "coffee-break" exams, as sources of "no change" truth along with a description of their usage as an estimate of the null hypothesis in assessing true change.

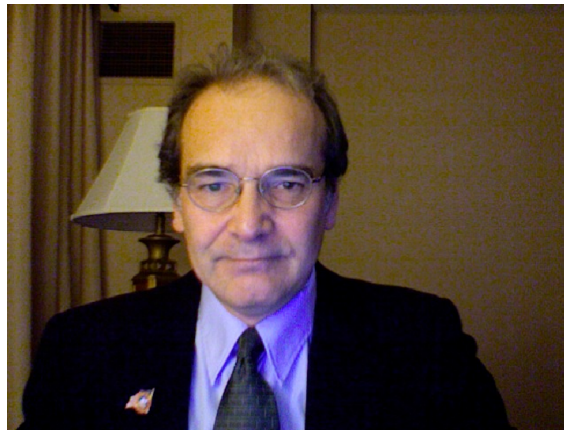
Dr. Meyer is principal investigator of an NCI program project (P01 CA087634) Meyer (PI) entitled "Automatic Three Dimensional (3D) Registration for Enhanced Cancer Management". The overall goal of the program project is to change current clinical paradigms through the support of accurate, early detection and measurement of breast cancer response to chemotherapy (Projects 1 & 3), and presurgical motor and temporal language cortex evaluation of brain function (Project 2) through the development, application and testing of robust and sophisticated registration and related signal processing tools.

#### **EDUCATION:**

Colorado State University, Ft. Collins, CO	M.S.	1969	Electrical Engineering
Iowa State University, Ames, Iowa	Ph.D.	1972	Biomedical Engineering

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**David F. Moore, MD, PhD**

**Dr. David F. Moore, BA, BSc, MB, ChB, MD, PhD, Dip PH, MRCP(I), ABNP (Neurology and Vascular Neurology):** Dr. Moore is a certified neurologist and vascular neurologist (ABNP) with extensive expertise in neuro-imaging, fluid dynamics, bio-informatics and mathematical biology. He has previously carried out investigations involving transcranial Doppler (TCD), positron emission tomography (PET), arterial spin tagging (AST), laser Doppler flow studies, magnetic resonance elastography (MRE), peripheral vessel M mode and B mode ultrasound scanning, analysis of neuro-imaging data, gene microarray data and UNIX system administration. Dr Moore trained at Imperial College (London), New York Hospital and the National Institutes of Health (Bethesda, Maryland). He is currently National Scientific Advisor, Defense and Veterans Brain Injury, headquartered at Walter Reed Army Medical Center, Washington DC, Lead Scientist DVBIC – AFIP Laboratory of Traumatic Brain Injury, TBI Scientific Advisor to the Defense Centers of Excellence and Visiting Scientist at MIT and the Institute of Soldier Nanotechnology.

#### **Expertise**

Neurology	Bio-Informatics	Traumatic Brain Injury
Genomics	MRI	Computational Biology
Fluid Dynamics	Image Processing	Blast Physics

#### **Discipline**

NEUROSCIENCES	Cerebral ischemia
NEUROSCIENCES	Trauma/Nervous System
RADIOLOGY	Magnetic Resonance Imaging/Spectroscopy
FLUID MECHANICS	Fluid Mechanics/Hemodynamics
COMPUTER SCIENCE	Modeling and Simulation Studies
GENETICS	Genomics
INFORMATION TECHNOLOGY	Bio-informatics
COMPUTER SCIENCE	Image Processing

#### **Research Program**

Cerebral hemodynamics, neurogenetics, neuroprotection, neuroregeneration, and neurotherapeutics as more recently applied to traumatic brain injury particularly blast related traumatic brain injury and recovery. The research approach adopted is both top-down and bottom-up with development of sequential and parallel hypothesis generation. This paradigm approach is applied in a ‘translational’ manner to problem-solve pressing patient issues in an iterative bench-to-bedside approach.



**John Moreland, Ph.D.**

Dr. John Moreland received a Ph.D. in Physics from the University of California Santa Barbara in 1984. Currently he is the Project leader of Microsystems Program in the Electromagnetic Division at NIST. Project members are taking an approach based on chip-scale microsystems and nanosystems to advance instrumentation by improving sensitivity, portability, cost, and traceability to fundamental constants. The research has traditionally focused on the data storage, electronics, and communication industries and is currently exploring applications in medicine and bioengineering. Recent programs include magnetic manipulation and measurement of single molecules in microfluidic environments, engineered radio-frequency tags for magnetic resonance imaging (MRI) and microfluidics, precision cantilevers for transfer standards and intrinsic force measurements, microfabrication of chip-scale atomic clocks and magnetometers, and integration of chip-scale MRI microscopy systems. Dr. Moreland has published over 100 peer reviewed papers and has been awarded 4 patents.

**Some recent publications:**

"Micro-engineered local field control for high-sensitivity multi-spectral MRI" Nature, 10, 1058-1064, 2008, (G. Zabow, S. Dodd, J. M. Moreland, A. P. Koretsky).

"Controlled Transport of Magnetic Particles Using Soft Magnetic Patterns" App. Phys. Lett., 93, pp. 1-3, 2008 (R. Conroy, G. Zabow, J. M. Moreland, A. P. Koretsky).

"Design and fabrication of a micromachined multi-spectral magnetic resonance imaging agent" J. Micromechanics and Microengineering, 19, 1-10, 2009, (G. Zabow, A. P. Koretsky, J. M. Moreland).

"The fabrication of uniform cylindrical nanoshells and their use as spectrally tunable MRI contrast agents," Nanotechnology, 20, 385301, 2009 (Zabow G, Dodd SJ, Moreland J, A. Koretsky).

**Biomagnetics**

This NIST program is developing new metrology and standards for biomedical imaging based on magnetic resonance, magnetic nanoparticles, and low field sensing of biomagnetic fields. Micromechanical and magnetic resonance systems are being developed to characterize nanomagnetic systems and their use for measuring, detecting, and manipulating biomolecules for health and national security applications.

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### **Susumu Mori, Ph.D.**

Susumu Mori is Professor in the Department of Radiology at the Johns Hopkins University School of Medicine. He has been working at Hopkins since 1991, including 5 years of graduate work. Dr. Mori received his bachelors and masters degree from Tokyo University of Fisheries. In 1996, he received his doctorate from Johns Hopkins University in Biophysics. He also completed his post-doctoral fellowship at Johns Hopkins.

Dr. Mori's research interests to develop new MRI technologies to study brain neuroanatomy. His recent works include diffusion tensor imaging and microimaging to study brain white matter diseases and brain development. Dr. Mori is the architect and developer of DTI Studio, a widely used software system with Processing Tools and Environment for Diffusion Tensor Imaging.

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**Pratik Mukherjee, M.D., Ph.D.**

Dr. Mukherjee's research focus is on technical development and clinical application of advanced diffusion MRI methods, including diffusion tensor imaging (DTI) and high angular resolution diffusion imaging (HARDI) techniques such as *q*-ball imaging. Recent work in collaboration with the laboratory of Dr. Daniel B. Vigneron includes the initial application of ultra-high field (7 Tesla) diffusion MRI to the study of the complex white matter architecture of the human brain *in vivo*. I also currently have ongoing prospective longitudinal clinical research studies of DTI, HARDI, and related fiber tractography techniques for evaluating changes in white matter connectivity during human brain development and following traumatic brain injury.

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<b>Education:</b>	Cornell University School of Medicine	1995
<b>Residencies:</b>	Washington University Medical Center	2000
<b>Fellowships:</b>	Washington University Medical Center	2002

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**Ponnada A. Narayana, Ph.D., M.Sc.**

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Research Interests:

- Quantitative magnetic resonance imaging
- In vivo magnetic resonance spectroscopic imaging
- Instrumentation
- Ultrafast imaging
- Automatic image segmentation

The main emphasis of Dr. Narayana's research group is the development and application of advanced magnetic resonance imaging (MRI) techniques, including selective tissue imaging, magnetic resonance spectroscopic imaging, and diffusion tensor imaging to neurological disorders and central nervous system trauma. Another major emphasis of our research is the development of novel image processing techniques that are robust and automatic for handling large number of images that are typically encountered in multi-center clinical trials. The laboratory facilities include a 7 Tesla, state-of-the-art MRI scanner dedicated to animal studies, a research dedicated 3 Tesla whole body scanner (to be installed in June 2004), an image processing laboratory, and a fully equipped animal surgical suite.

PhD Physics, Indian Institute of Technology, Kanpur, India, 1969

MSc Nuclear Physics, Andhra University, Andhra, India, 1965

BSc Andhra University, Andhra, India 1963

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**Carole L. Palumbo, Ph.D.**

Dr. Palumbo is a Research Assistant Professor of Neurology at Boston University School of Medicine and a Principal Investigator at the US Army Research Institute of Environmental Medicine. She earned her B.A. from Smith College and went on to receive her Ph.D. in Behavioral Neuroscience from Boston University School of Medicine. Dr. Palumbo's expertise is in using various neuroimaging techniques to study patients with aphasia, an area in which she has more than 25 years of experience. In addition she has worked on neuroimaging projects in the areas of Gulf War Illness, environmental exposures, aging and dementia.

1: Heaton KJ, Palumbo CL, Proctor SP, Killiany RJ, Yurgelun-Todd DA, White RF. Quantitative magnetic resonance brain imaging in US army veterans of the 1991 Gulf War potentially exposed to sarin and cyclosarin. *Neurotoxicology*. 2007 Jul;28(4):761-9.

2: Devine SA, Kirkley SM, Palumbo CL, White RF. MRI and neuropsychological correlates of carbon monoxide exposure: a case report. *Environ Health Perspect*. 2002 Oct;110(10):1051-5.

3: Kurowski KM, Blumstein SE, Palumbo CL, Waldstein RS, Burton MW. Nasal consonant production in Broca's and Wernicke's aphasics: speech deficits and neuroanatomical correlates. *Brain Lang*. 2007 Mar;100(3):262-75.

4: Naeser MA, Martin PI, Baker EH, Hodge SM, Sczerzenie SE, Nicholas M, Palumbo CL, Goodglass H, Wingfield A, Samaraweera R, Harris G, Baird A, Renshaw P, Yurgelun-Todd D. Overt propositional speech in chronic nonfluent aphasia studied with the dynamic susceptibility contrast fMRI method. *Neuroimage*. 2004 May;22(1):29-41.

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**Xavier Pennec, Ph.D.**

I am currently a Research Director (Senior research Scientist) at the ASCLEPIOS team at INRIA Sophia-Antipolis (France). I hold a PhD from the Ecole Polytechnique (Paris) in 1996, and I was a post-doctoral associate at MIT AI-lab before joining INRIA in 1998. My main research axes are about image processing and statistics on geometric data, in particular for medical image analysis, and biomedical image registration. Over the last years, these fields have gradually converged towards computational anatomy, which aims at statistically describing the normal and abnormal anatomy of organs across populations. I am particularly interested by the mathematics involved in these fields: statistical computing on Riemannian manifolds and potentially other geometric structures (Lie groups, information geometry...).

## **Selected bibliography**

- Xavier Pennec, Pierre Fillard, and Nicholas Ayache. [A Riemannian Framework for Tensor Computing](#). International Journal of Computer Vision, 66(1):41-66, January 2006.
- Vincent Arsigny, Pierre Fillard, Xavier Pennec, and Nicholas Ayache. [Log-Euclidean Metrics for Fast and Simple Calculus on Diffusion Tensors](#). Magnetic Resonance in Medicine, 56(2):411-421, August 2006.
- Jean-Marc Peyrat, Maxime Sermesant, Xavier Pennec, Hervé Delingette, ChenYang Xu, Eliot R. McVeigh, and Nicholas Ayache. [A Computational Framework for the Statistical Analysis of Cardiac Diffusion Tensors: Application to a Small Database of Canine Hearts](#). IEEE Transactions on Medical Imaging, 26(11):1500-1514, November 2007.
- Pierre Fillard, Xavier Pennec, Vincent Arsigny, and Nicholas Ayache. [Clinical DT-MRI Estimation, Smoothing and Fiber Tracking with Log-Euclidean Metrics](#). IEEE Transactions on Medical Imaging, 26(11):1472-1482, November 2007. Boon Thye Thomas Yeo, Tom Vercauteren, Pierre Fillard, Jean-Marc Peyrat, Xavier Pennec, Polina Golland, Nicholas Ayache, and Olivier Clatz. [DT-REFinD: Diffusion Tensor Registration with Exact Finite-Strain Differential](#). IEEE Transactions on Medical Imaging, 28(12):1914-1928, December 2009.
- Stanley Durrleman, Pierre Fillard, Xavier Pennec, Alain Trouvé, and Nicholas Ayache. [A Statistical Model of White Matter Fiber Bundles based on Currents](#). In Information Processing in Medical Imaging (IPMI'09), volume 5636 of LNCS, pages 114-125, 2009.

## Recent projects

- **Karametria**: Statistical analysis of the geometry of brain structures, French ANR-Blanc research project (<http://sites.google.com/site/karametria/home>)
- **Brain Atlas**: associated team with LONI at UCLA (<http://www-sop.inria.fr/asclepios/projects/UCLA/>)
- **ARC BrainVar**: modeling the anatomical variability of the brain, INRIA Cooperative Research Initiatives (<http://www-sop.inria.fr/asclepios/projects/ARCBrianVar/>)
- **Health e-Child**: an integrated healthcare platform for European pediatrics. (<http://www.health-e-child.org/>). Illustrations and details on our work on [disease modeling](#) in this project.
- **NeuroLOG**: Software technologies for integration of process, data and knowledge in medical imaging (<http://neurolog.polytech.unice.fr/>).
- Master of Computer Science in Computational Biology from Nice Sophia Antipolis University

## Some online presentations

- [Statistical Computing on Manifolds for Computational Anatomy](#). Video of the lecture at [Emerging Trends in Visual Computing \(ETVC'08\)](#), Palaiseau, November 18-20, 2008.
- [A Riemannian Framework for Diffusion Tensor Analysis \(8 Mb\)](#). Slides of the presentation at the MICCAI'08 Workshop on Diffusion MRI, New York, September 6, 2008.

## Journals, Conferences and Workshops involvement:

- [Medical Image Analysis Journal](#) (MedIA) (associate editor)
- [The international Journal of Computer Vision](#) (IJCV), (associate editor)
- [SIAM Journal of Imaging Science](#) (SIIMS), (associate editor)
- [MFCA 2006](#) and [MFCA 2008](#): 1<sup>st</sup> and 2<sup>nd</sup> Workshop on Mathematical Foundations of Computational Anatomy (chair)
- [Medical Image Computing and Computer Assisted Interventions \(MICCAI\)](#) (PC / Review committee)
- [IPMI](#) conferences (Review committee)

## Contacts and information

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**Carlo Pierpaoli, MD. PhD.**

Carlo Pierpaoli received the M.D. *summa cum laude* in 1989 at the University of Milan, Italy. Thesis: "Characterization of the peripheral benzodiazepine receptor in human lymphocytes. Modifications in neuropsychiatric disorders."

He is board certified in Neurology (European Certification) in 1993. He received also a Ph.D. in Neurological Sciences, at the University of Milan, for his thesis: "Tensor imaging of water diffusion in the human brain."

Carlo Pierpaoli is presently a Staff Scientist in the Program on Pediatric Imaging and Tissue Sciences, NICHD, NIH. He is member of the NIH In vivo NMR Center Steering Committee and member of the advisory committee for the Pediatric Neuroimaging initiative of NINDS, NIDA, NIMH, and NICHD.

He received in 1996 of the NIH Award of Merit for performing the first diffusion tensor imaging studies of the human brain and in 2006 the NIH Director's Merit Award for exemplifying intra-institute collaboration in creating a valuable resource for the developmental and clinical neuroscience community. He is Fellow of the International Society of Magnetic Resonance in Medicine (ISMRM), and has served as a member of the ISMRM Annual Program committee and Chair of the Diffusion-Perfusion study group.

His main professional interest is studying brain structure and function in health and disease with non-invasive imaging techniques. Recently, he worked on improving diffusion tensor MRI methods for the quantitative characterization of water diffusion in the brain.

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**Sunder S. Rajan, Ph.D.**

The rapid development of MRI technology has spawned a number of applications that allow functional characterization of tissue. These include perfusion imaging, diffusion imaging, elastography and thermometry. Many of these methods are finding use as markers of disease and as treatment response indicators. My main research interests centers on the validation of some of the functional imaging markers used in MRI. Some of these MRI derived parameters have recently been proposed for use as end points in multicenter clinical trials. As the reproducibility and variability of these measures have not been adequately validated, there is a need to validate the MRI techniques with regard to the reproducibility, variability and measurement errors. Currently we are evaluating the use of hollow fiber cartridge flow systems to mimic dynamic contrast enhanced (DCE) tissue perfusion studies.

**EDUCATION:**

PhD (Chemistry) at University of Chicago, 1984

Post-doctoral research on in vivo NMR at Johns Hopkins University, 1986

**PUBLICATIONS (selected):**

1. Rajan, Sunder S. *MRI: A Conceptual Overview*, 1st edition, 1997 (Springer-Verlag, New York).
2. Lin CS, Rajan SS, Gold J. A novel multi-segment surface coil for neuro-functional magnetic resonance imaging. *Magn Reson Med*. 1998 Jan;39(1):164-8.
3. Wear KA, Myers KJ, Rajan SS, Grossman LW. Constrained reconstruction applied to 2-D chemical shift imaging. *IEEE Trans Med Imaging*. 1997 Oct;16(5):591-7.
4. Levy LM, Gulya AJ, Davis SW, LeBihan D, Rajan SS, Schellinger D. Flow-sensitive magnetic resonance imaging in the evaluation of cerebrospinal fluid leaks. *Am J Otol*. 1995 Sep;16(5):591-6.
5. Schellinger D, LeBihan D, Rajan SS, Cammarata CA, Patronas NJ, Deveikis JP, Levy LM. MR of slow CSF flow in the spine. *AJNR Am J Neuroradiol*. 1992 Sep-Oct;13(5):1393-403.
6. Rajan SS, Rosa L, Francisco J, Muraki A, Carvlin M, Tuturea E. MRI characterization of 9L-glioma in rat brain at 4.7 Tesla. *Magn Reson Imaging*. 1990;8(2):185-90.
7. Rajan SS, Patt RH, Jarso S, Mellusi M, Carvlin M, Lossef S. An extended-length coil design for peripheral MR angiography. *Magn Reson Imaging*. 1991;9(4):493-5.

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**Stephen Rao, Ph.D.**

Stephen M. Rao, Ph.D., ABPP-Cn is the Ralph and Luci Schey Chair and Director of the Schey Center for Cognitive Neuroimaging at the Cleveland Clinic and Professor of Medicine in the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University. He obtained his Ph.D. in Clinical Psychology from Wayne State University (Detroit) and completed a predoctoral internship at Rush-Presbyterian-St. Luke's Medical Center (Chicago). Prior to joining the Cleveland Clinic in May of 2007, he was Director of the Functional Imaging Research Center and Professor of Neurology (Neuropsychology) at the Medical College of Wisconsin (Milwaukee). He has authored over 130 scientific papers/book chapters and edited three books.

His primary research areas involve the application of functional MRI to study memory (working, episodic, and semantic); selective attention; motor control; temporal information processing; and conceptual reasoning in healthy young and older participants, individuals in the preclinical stage of Huntington's and Alzheimer's diseases; and in patients with multiple sclerosis, Parkinson's disease, and Traumatic Brain Injury. He has been a recipient of a National Institutes of Health Research Career Development Award and has received funding from National Institute of Neurological Disorders and Stroke, National Institute of Mental Health, National Institute on Aging, US Department of Defense, Charles A. Dana Foundation, and National Multiple Sclerosis Society.

He is the Editor of *Neuropsychology* (published by the American Psychological Association), has served as the Associate Editor of *Journal of the International Neuropsychological Society*, and has been a member of the editorial boards of eight other journals. He is currently the President of the International Neuropsychological Society (INS) and has served on the board of trustees of the INS, board of directors of the American Board of Clinical Neuropsychology, and served as chairman of the scientific program committee for the INS annual meeting.

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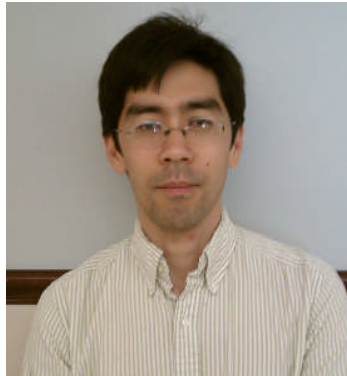
**Gerard Riedy, Ph.D., M.D.**

Dr. Riedy is Assistant Professor, Uniformed Services University, Bethesda, MD. He completed a fellowship in Neuroradiology at Johns Hopkins University, Baltimore, MD after radiology residency at Bowman Gray-Wake Forest University, Winston-Salem, NC. He received an M.D. at the University of Colorado School of Health Sciences Center (UCHSC), Denver, CO and Ph.D. in Biochemistry, Northern Illinois University, DeKalb, IL. Since 2007, Dr. Riedy has served as the Principal Investigator of the Congressionally Directed Medical Research Project, "National Capital Consortium TBI Neuroimaging Core".

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### **Ken Sakaie, Ph.D.**

Ken Sakaie, Ph.D., is a Project Staff Member in the Imaging Institute at the Cleveland Clinic main campus. He is a consulting physicist for multi-center research studies with MRI components and supervises the hardware and research activity on MRI scanners. In addition he has developed new MRI research methods, among other activities.

Dr. Sakaie earned his master's and doctoral degrees in physics from the University of Illinois at Urbana-Champaign in Urbana, Ill, followed by postdoctoral fellowships at Massachusetts General Hospital and Northwestern University.

Dr. Sakaie has published a number of peer-reviewed articles on topics related to magnetic resonance. His current research interests are: advanced diffusion tensor and BOLD functional MRI to improve characterization of progression of multiple sclerosis and to improve efficacy of Deep Brain Stimulation treatment of Parkinson's Disease; current density imaging for direct in vivo measurement of current spread of deep brain stimulators; and novel imaging methods for in vivo determination of tissue heating associated with metallic implants in patients undergoing MRI.

He is a member of the International Society for Magnetic Resonance in Medicine.

#### Education & Fellowships

Doctorate - University of Illinois at Urbana-Champaign  
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Undergraduate - Stanford University  
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**John Schenck, MD, PhD**

Dr. John Schenck, a principal scientist in the MRI Lab at General Electric's Global Research Center in Niskayuna, has been awarded the International Society for Magnetic Resonance in Medicine's Gold Medal in 2009. The award, the society's highest individual honor, recognizes those who have made major research contributions to magnetic resonance imaging.

Dr. Schenck was a member of the original research team that enabled GE to introduce the first clinically viable high field MRI scanner in the early 1980s. He served as a principal leader on the research team that achieved the first whole body imaging at 1.5 tesla in 1982. This achievement was instrumental in making possible the introduction of GE's breakthrough scanner.

Roberta A. Kravitz, Executive Director, International Society for Magnetic Resonance in Medicine (ISMRM), said, "Dr. Schenck exemplifies all of the attributes we look for in a Gold Medal recipient and so much more. His research contributions have had a tremendous impact in advancing the state-of-the-art in MRI technology. But even beyond pushing the limits of technology, his many published works on MRI safety have served as a guide to the entire industry in how it is regulated and managed."

"Dr. John Schenck was a key part of the team at GE that helped put magnetic resonance imaging on the map back in the early 1980s," said Mark Little, Senior Vice President and Director of GE Global Research. "MRI is having such a positive impact in healthcare today because of research pioneers like John who helped bring it to market and made important advancements along the way. We're all very proud to see John recognized among so many of his peers with ISMRM's most prestigious award."

Schenck noted "it has been a wonderful opportunity to work with the people and the resources available at GRC on a technical opportunity as full of technical challenges and medical significance as MRI. All of us are continually aware of the major impact MRI has made on medical practice and healthcare in general and how fortunate we have been to be able to work in this area." Dr. Schenck first joined GE as a research scientist in 1965. In 1978, he became the first full-time GE researcher to work in MRI technologies. Over the years, he has made many important research contributions in MRI and emerged as a leader in the industry who is often called upon for his viewpoints.

Major highlights include:

- Major inventions in the areas of radiofrequency and gradient coils required in MRI. This included leading a team at Global Research that produced the first clinically practical whole-body RF coil operating at 3 tesla.
- Conducting extensive studies into the use of high field MRI to investigate brain iron abnormalities in neurodegenerative disorders such as Alzheimer's and Parkinson's

diseases. His studies have provide critical insights on how MRI can help in promoting earlier detection of these debilitating diseases. Today, he is co-directing a joint Albany Medical College/GE MR research center devoted to high field MR research on neurodegenerative diseases.

- Writing extensively on issues of MR safety, including the role of magnetic susceptibility in MRI and the development of interventional MRI. His papers have frequently been cited by the FDA in their guidelines for MR safety and compatibility.
- Serving as a reviewer for many MRI journals. He received the SS Greenfield Award of the American Association of Physicists in Medicine (AAPM) for best paper published in the Association publication, Medical Physics, in 1993. Dr. Schenck has received many prestigious honors during his career. He is a Fellow of the American Physical Society and holds a Coolidge Fellowship, which is highest individual award for technical excellence at GE Global Research.

Dr. Schenck received a PhD in Solid State Physics from RPI in 1965 and an MD degree from Albany Medical College in 1978. In addition to his career as a research scientist at GE, he served as an Associate Professor of Electrical Engineering at Syracuse University in the early 1970s. In addition to his technical work, he treated thousands of patients as an emergency room physician at Ellis Hospital in Schenectady during the 1980s and 1990s.

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**Norbert Schuff, Ph.D.**

The overall focus of my research is twofold: a) developing novel methods of quantitative magnetic resonance imaging and b) identifying MRI based markers for better diagnosis, prognosis, and monitoring treatment of neurodegenerative diseases, such as Alzheimer's and Parkinson's disease.

The focus of my technically oriented research is on developing optimized high field MRI techniques (3 & 4Tesla). In particular, my research is aimed to improve detection of brain perfusion by developing better strategies for arterial spin labeling (ASL), detection of white matter fiber bundles by improving acquisition and evaluation of diffusion tensor imaging (DTI) as well as diffusion spectrum imaging (DSI). Furthermore, I am developing and testing new statistical approaches for the analysis of multimodality imaging data, such as multivariate statistics, canonical correlations, non-parametric and kernel methods.

The focus of my clinically oriented research aims to establish MRI based biomarkers of various types of neurodegenerative disorders, including Parkinson's disease (PD) as well as psychiatric conditions, such as Posttraumatic Stress Disorder (PTSD) utilizing multimodal imaging measurements I have also been involved in the preparation, and execution of MRI multicenter studies for several clinical trials, the Alzheimer's Disease neuroimaging initiative (ADNI) and Frontotemporal Dementia imaging initiative (FDNI). I have published over 160 peer-reviewed scientific articles, 30 book chapters and reviews, and numerous abstracts.

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### **Manbir Singh, Ph.D.**

After receiving his Ph.D. in Physics from the University of California, Los Angeles (UCLA) in 1971, Dr. Singh conducted post-doctoral studies at UCLA in Biomedical Physics at the Laboratory of Nuclear Medicine and Radiation Biology, where he worked on the first PET camera with Dr. Cho. Subsequently he spent one year at the Mayo Clinic, Rochester, Minnesota as a Visiting Scholar of the American Heart Association where he did the first studies in SPECT. He joined the Department of Radiology at USC in 1977 and received a joint appointment in Biomedical Engineering in 1988.

In 1976, Dr. Singh received a Visiting Scientist Award from the American Heart Association to pursue research in nuclear medicine and dynamic X-ray computed tomography for imaging the heart at the Mayo Clinic in Rochester, Minnesota. Dr. Singh was a part of an interdisciplinary team which developed the Dynamic Spatial Reconstructor (DSR), a revolutionary CT scanner for three-dimensional imaging and visualization of the beating heart. Dr. Singh pioneered the use of single photon emission computed tomography (SPECT) using a rotating scintillation camera to detect and quantify acute myocardial infarctions in three dimensions, and he was one of the first investigators to demonstrate the synergism of X-ray CT and nuclear medicine SPECT imaging in detecting and visualizing both the anatomy and function of the heart.

In 1980 he was funded by NCI to develop a new electronically collimated SPECT camera design proposed by him to improve the sensitivity and high-energy imaging capabilities of mechanically collimated scintillation cameras. He successfully designed a prototype scintillation camera coupled to an array of germanium semiconducting detectors to collimate medium (140keV) to high-energy (661 keV) gamma rays based on recording Compton scattered photons from the germanium onto the uncollimated scintillation camera. New cone-beam reconstruction algorithms were also developed to reconstruct 3D images from these counts. Dr. Singh was the nationally elected AdCom representative for Nuclear Medical Sciences in the IEEE Nuclear and Plasma Society (NPSS) from 1986-1989, co-founder of the IEEE Medical Imaging Conference in 1990, the technical chair for Nuclear Medical Sciences within IEEE NPSS from 1991 -1993, and Scientific Program Chair of the 1992 and 1993 IEEE Medical Imaging Conferences. During the mid 80s he also proposed the concept of using magnetoencephalography (MEG) to image the electrical activity of distribute neuronal sources inside the human brain and operated a SQUID MEG lab at USC.

His current interests are in functional MRI and DTI tractography with applications of DTI to Alzheimer Disease and Traumatic Brain Injury. He is the founder and Director of the Neuroimaging core at USC, which develops new methodology in fMRI and DTI. He has developed new approaches to improve the spatio-temporal resolution in fMRI and novel methods to quantify brain connectivity using DTI. Dr. Singh is also the founding director of the graduate program in Biomedical Imaging within the Department of Biomedical Engineering at USC.

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**Douglas H. Smith, M.D.**

Douglas H. Smith serves as Director of the Center for Brain Injury and Repair (CBIR) and is the Robert A. Groff Endowed Professor of Neurosurgery at the University of Pennsylvania. Penn's multidisciplinary CBIR includes over twenty-five principal investigators and their laboratory staff collectively studying mechanisms, diagnosis and potential treatments of traumatic brain injury. Over the last 18 years, Dr. Smith has devoted his full-time efforts to neurotrauma research following completion of fellowships in both molecular biology and neurotrauma at the University of Connecticut. He has been an active member of the National Neurotrauma Society and currently serves as an officer. In addition, Dr. Smith is director of a multi-center NIH program grant on mild traumatic brain injury and he oversees an NIH training grant for brain injury research. His laboratory's research interests include investigating the biomechanical effects of traumatic brain injury, imaging techniques to diagnose diffuse axonal injury, and the link between diffuse axonal injury and Alzheimer's disease. Dr Smith's laboratory has also engineered nervous tissue constructs that have been shown to repair spinal cord and nerve damage. These collective efforts have resulted in over 140 published reports.

Today there are no treatments available to halt the progressive damage initiated by brain trauma. Yet there is hope, based largely on research at the Penn Center for Brain Injury and Repair at the University of Pennsylvania Health System, directed by Dr. Smith. The Penn Center for Brain Injury and Repair (previously called the Head Injury Center) has been in existence for more than 30 years and is one of only five designated Brain Injury Centers nationwide, an honor bestowed by the National Institutes of Health.

Over 25 principal investigators and their research personnel form the Center for Brain Injury and Repair. They represent a diversity of disciplines that span Neurosurgery, Bioengineering, Pharmacology, Pathology, Neurology, Pediatrics, Neuroradiology, Rehabilitation, and Emergency Medicine. This team comprises one of the strongest, most integrated research teams in the world. Working in a highly collaborative environment, these researchers are studying ways to significantly improve the quality of life for people suffering from traumatic brain injury (TBI) and to prevent the "secondary" or delayed injuries that are initiated by brain trauma.

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**A. Gregory Sorensen, M.D.**

Dr. Sorensen's research focus has been on bringing novel technical developments in functional magnetic resonance imaging to the investigation of neurologic disease and the care of patients. Additionally, he has worked to bring radiology tools to clinical research, particularly in the evaluation of novel interventions. In the clinical trials arena, this work has been in concert with industrial sponsors who wish to use radiologic techniques to rapidly evaluate new therapies. His techniques have been utilized by 56 centers throughout the world in phase II and III trials of novel oncology agents such as gene therapy. Dr. Sorensen is also active in pursuing the development of novel neuroimaging, with active work in optical imaging, magnetoencephalography, and very high field human MRI (3T and above).

Dr. Sorensen is a neuroradiologist with significant experience in clinical care, clinical trials, and translational research. As an active researcher, Dr. Sorensen is well-known for his innovative research in the field of diffusion and perfusion MR imaging. Dr. Sorensen serves as the Associate Director of the Martinos Center for Biomedical Imaging, Co-director of the Cancer Imaging Program at the Dana Farber / Harvard Cancer Center, and Director of the Biomedical Imaging Core of the MGH General Clinical Research Center. Dr. Sorensen also served as the Medical Director of EPIX Medical, Inc., and oversaw several successful multi-center Phase III clinical trials involving more than 80 clinical sites around the world.

Dr. Sorensen received his BS in biology from California Institute of Technology, MS in Computer Science from Brigham Young, and MD from Harvard Medical School. Dr. Sorensen is Professor of Radiology at Harvard Medical School, and a faculty member at the Harvard-MIT Division of Health Sciences and Technology.

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**Karen A. Tong, M.D.**

Karen A. Tong is a neuroradiologist at Loma Linda University Medical Center with special expertise in neuroimaging of traumatic brain injury, including children. She completed a neuroradiology fellowship at the University of Utah. Prior work by Dr. Tong and Mark Haacke PhD, demonstrated the value of susceptibility weighted imaging (SWI) for detecting hemorrhagic diffuse axonal injury (DAI) in children, where it was five times more sensitive than conventional gradient echo imaging. She is a co-investigator for a NIH funded project (R01 NS054001-01A1) entitled: "Pediatric TBI and DAI: Normal Appearing Brain is not Normal", utilizing SWI, MR spectroscopy and Diffusion Tensor Imaging (DTI) to evaluate pediatric TBI. She is also currently involved in the NIH Pediatric TBI Common Data Elements (CDE) project.

She has published multiple peer-reviewed articles on TBI and SWI:

Babikian T, **Tong KA**, Galloway NR, Freier Randall MC, Obenaus A, Ashwal S. Diffusion-weighted imaging predicts neurocognition in traumatic brain injury. *Pediatr Neurol* 2009 Dec;41(6):406-12

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In addition, she has published several book chapters on TBI:

**Tong K**, Oyoyo U, Holshouser BA, Ashwal S, Medina LS. Chapter 7: Evidence-Based Neuroimaging for Traumatic Brain Injury in Children. In: Evidence-Based Imaging in Pediatrics. Medina LS, Applegate KE, Blackmore CC (eds). Springer, New York, NY, 2010: 85-102.

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**Peter C. M. van Zijl, Ph.D.**

Dr. van Zijl graduated cum laude with a Masters in Inorganic Chemistry and continued to obtain a Ph.D. in Mathematics and Physics from the Free University in Amsterdam, The Netherlands. His thesis focused on the description of molecular alignment in magnetic fields and the changes in the Nuclear Magnetic resonance (NMR) spectra related to this. After completing fellowships in Nuclear Magnetic Resonance (Carnegie Mellon University, Pittsburgh) and MRI (National Institutes of Health, National Cancer Institute), he became a Research Assistant Professor at Georgetown University in 1990. In 1992 he was invited to join the Department of Radiology at Johns Hopkins University Medical School, where he was promoted to Associate Professor (1992) and Professor (1997). In 1999 he became the founding director of the F.M. Kirby Research Center for Functional Brain Imaging at the Kennedy Krieger Institute. This Center has since been awarded status as a National Center for Biomedical Technology Research funded by the National Center for Research Resources. Dr. van Zijl is a fellow of the International Society for Magnetic Resonance in Medicine and has received the Society's gold medal award for scientific achievement. He also served on the Executive Committee of the Experimental NMR conference. He resides on the editorial boards of the journals: NMR in Biomedicine, Journal of Magnetic Resonance, Magnetic Resonance in Medicine, and the Journal of Cerebral Blood flow and Metabolism. He is an ad hoc member of several NIH review panels for several institutes.

Dr. van Zijl's present research focuses on developing new methodologies for using MRI and Magnetic Resonance Spectroscopy (MRS) to study brain function and physiology. In addition he is working on understanding the basic mechanisms of the MRI signal changes measured during functional MRI (fMRI) tests of the brain. Other interests are in mapping the wiring of the brain (axonal connections between the brain's functional regions) and the design of new technologies for MRI to follow where cells are migrating, and when genes are expressed. A more recent interest is the development of bioorganic biodegradable MRI contrast agents. The ultimate goal is to transform these technologies into fast methods that are compatible with the time available for multi-modal clinical diagnosis using MRI. He is especially dedicated to providing a comfortable scanning environment for children, where they can enjoy the experience in the MRI scanner. Dr. van Zijl's research is funded by several grants from the National Center for Research Resources and the National Institute of Biomedical Engineering and Bioengineering.

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**Carl-Fredrik Westin, Ph.D.**

Carl-Fredrik Westin is the founding director of Laboratory of Mathematics in Imaging (founded 2000), Department of Radiology, Brigham and Women's Hospital and Harvard Medical School, and Associate Professor of Radiology at Harvard Medical School, Boston.

His research interests include:

- Neuro Image Analysis
- Image Guided Therapy
- Manifold Learning for Imaging
- Diffusion MRI in Schizophrenia
- Diffusion MRI for Traumatic Brain Injury (TBI)

Carl-Fredrik Westin has (co)-authored over 180 publications, abstracts excluded, in the fields of computer vision, medical image analysis and image guided surgery, of which over 70 are in peer-reviewed international journals. He has served as a Guest Editor on several special issues on image analysis (IEEE Transactions on Medical Imaging, International Journal of Computer Vision, Signal Processing).

He has mentored 16 post-doctoral fellows with engineering and computer science background; 6 of them currently hold tenure track positions at different universities, 5 hold junior faculty positions, 3 have research positions in the medical imaging industry, and 2 are currently working in LMI. He has also supervised 12 PhD students and 15 MSc students.

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**Ross T. Whitaker, Ph.D.**

Dr. Whitaker is an Associate Professor in the [School of Computing](#) at the [University of Utah](#). He works in the [Scientific Imaging and Computing Institute](#), and he runs the [Image Processing Laboratory](#). He conducts research in image processing, computer vision, pattern recognition, and visualization. His approach to problems in these domains is usually based upon his background in differential geometry, differential equations, and signal processing.

His group is developing new methods in the areas of statistical shape analysis, MRI tissue segmentation, and diffusion tensor image processing and analysis. They are building shape analysis tools that can generate efficient statistical models appropriate for analyzing anatomical shape differences in the brain. They are developing a wide range of tools for diffusion tensor imaging, that span the entire pipeline from image processing to automatic white matter tract extraction to statistical testing of clinical hypotheses.

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### **John Whyte, M.D., Ph.D.**

Dr. Whyte is the Principal Investigator of the NCCRN and Director of Moss Rehabilitation Research Institute and Professor of Rehabilitation Medicine at Thomas Jefferson University. He is trained in PM&R with specialization in traumatic brain injury (TBI), and holds a PhD in experimental psychology. He has received funding from the NIH, NIDRR, the Department of the Army, and several private foundations for his research.

#### **The Neuro-Cognitive Rehabilitation Research Network**

This NCCRN is a collaborative effort of investigators at the Moss Rehabilitation Research Institute and the University of Pennsylvania to provide research infrastructure support and expert consultation to individuals interested in pursuing cognitive rehabilitation research.

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#### **Areas of Expertise**

- Attention deficits following TBI, including: their neuropathologic substrate; information processing, functional imaging, and naturalistic methods of assessment; their interrelationship with executive systems; and approaches to treatment
- Recovery from prolonged unconsciousness (the vegetative and minimally conscious states), including: predictors of recovery of consciousness; ethical and family coping issues; and studies of treatment intervention
- Research methodology, including: special methodologic challenges inherent in rehabilitation research; applications of single subject experimental design; and the role of treatment theory in shaping rigorous clinical efficacy studies
- Research career development

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#### **Programs of Research**

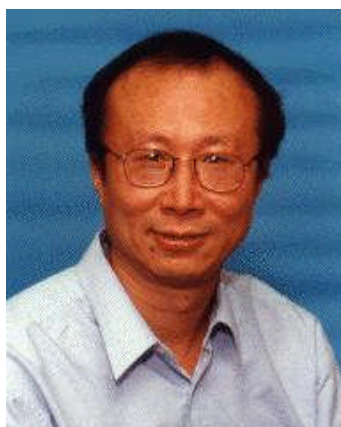
- The use of fMRI methods to understand the nature of TBI-related attention deficits and the effects of psychoactive drugs on attention networks and performance in TBI
- Assessment and treatment of attention deficits in lower level patients with TBI who cannot participate in formal testing or functional imaging
- Improving assessment and treatment for vegetative and minimally conscious patients

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**Jianhui Zhong, Ph.D.**

Prof. Zhong received his B.S. in Physics from Nanjing University, China, in 1982. He pursued his graduate study in experimental condensed matter physics at Brown University, receiving his Ph.D. in 1988. Prof. Zhong then went to the Yale University School of Medicine as a post-doctoral fellow in the emerging field of medical Magnetic Resonance Imaging (MRI) and joined the Yale faculty first as an Assistant Prof. in 1991, and then as an Associate Prof. in 1997. Prof. Zhong joined the University of Rochester in 1997. He was promoted to Professor of Radiology, Physics, and Biomedical Engineering in 2004. He currently serves as Director of MRI Research and Associate Director of the Rochester Center for Brain Imaging at the University of Rochester. Prof. Zhong has also been a visiting professor in several institutes, including the Chinese Science Academy, Tsinghua University, and Xiamen University, and has been serving on the Editorial Board of Magnetic Resonance Imaging, Medical Physics and two other journals. He has received Dean's Research Award from the Yale School of Medicine in 1996, and a URM Research Excellence Award in 2004.

Prof. Zhong's research activities, within the field of Biological Physics, involve studies of MRI signal changes in complex biological systems related to underlying physical processes such as molecular diffusion and variation of magnetic susceptibility. He is also involved in the development of novel MRI techniques. Understanding some of the important physical and physiological properties of biological tissues has led to new methods for the early detection of acute stroke, and to the development of brain functional MRI (fMRI). The experimental techniques used in Prof. Zhong's group include imaging in phantoms, extracted tissues, live animals, and humans, as well as computer simulations of magnetization in the heterogeneous environments that resembles tissues, and advanced imaging processing and statistical analysis.

Prof. Zhong's recent work includes: modeling of reduced diffusion in brain ischemia; diffusion-weighted MRI for detection of neuronal electrical activities and status epilepticus; quantitative measurements of tumor oxygenation and flow; DTI in mild traumatic brain injury (mTBI) and neurological impairment in HIV patients, and development of intermolecular multiple-quantum coherence (iMQC) MRI for brain function and metabolite measurements.

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**Geoffrey S.F. Ling, M.D., Ph.D.**

COL Geoffrey Ling, U.S. Army, is professor and vice-chairman of neurology at the Uniformed Services University of the Health Sciences (USUHS), director of neuro critical care at Walter Reed Army Medical Center and attending neuro critical care physician at Johns Hopkins Hospital. He is an active duty Colonel in the U.S. Army and the only board certified neuro critical care specialist in the Department of Defense. He served in Afghanistan and Baghdad, Iraq.

COL Ling leads the neurotrauma laboratory at USUHS. The focus areas are basic and applied research in traumatic brain injury with studies on the role of cytokines and cell cycle regulators in central nervous system inflammation and cell death as well as application of novel technologies and pharmacologic agents to diagnosis and treatment of this disease. He has received numerous national awards and has published over 100 peer-reviewed journal articles, reviews and book chapters, including Cecil's Textbook of Medicine.

COL Ling is also a program manager with the Defense Advanced Research Projects Agency. His portfolio focuses on restoring injured warfighters and preventing future injury. These programs include the development of advanced prosthetic limbs, pre-symptomatic disease detection, and determining causes of and potential mitigation strategies for TBI caused by explosion.

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**Max Wintermark, M.D.**

Dr. Max Wintermark is a graduate of medicine from Lausanne University in Switzerland. He received his professional training in radiology from Lausanne University Hospital, as well as from the University of California San Francisco. A pioneer in the development of Perfusion-CT with patented work pertaining to the technique, Dr. Wintermark is a published author of numerous articles and textbook chapters in the field of cerebrovascular imaging. Dr. Wintermark is currently an Associate Professor and Director of the Neuroradiology Section at the University of Virginia.

Dr. Wintermark led the Acute Stroke Imaging Research Roadmap project, which inspired the DMRI of TBI workshop. Dr. Wintermark was a founding member of the **STIR - Stroke Imaging Repository**.

- Wintermark M, et al. Acute stroke imaging research roadmap. AJNR Am J Neuroradiol. 2008 May;29(5):e23-30. [AND] Stroke. 2008 May;39(5):1621-8.

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**Regina E. McGlinchey, Ph.D.**

*Regina McGlinchey, Ph.D.* is the Co-Director of the GNL, an Associate Professor of Psychology in the Department of Psychiatry at Harvard Medical School, and the Director of the Translational Research Center for TBI and Stress Disorders, a VA RR&D Center of Excellence.

Dr. McGlinchey's research is devoted to expanding our knowledge of the normal operations of cognitive functions such as attention, perception, language, memory, and learning through the study of individuals for whom these functions have become compromised due to stroke, disease or dementia. Most recently, she focused on the founding of a new funded VA Rehabilitation Center of Excellence, for which she serves as Principal Investigator and Director, called the "Translational Research Center for TBI and Stress Disorders" (TRACTS). This new research Center focuses on innovations in the diagnosis and treatment of traumatic brain injury (also called concussion) and stress-related disorders facing a large number of OEF/OIF veterans. This Center will conduct state-of-the-art research studies that aim to understand how mild TBI and related stress disorders impact the brain leading to problems in thinking abilities, as well as family and work life. Several of the research projects focus on the development of innovative treatments that target both TBI and related stress disorders simultaneously, in order to maximize recovery.

She developed and maintained one of only a few Classical (Pavlovian) Eyeblink Conditioning Laboratories in the country to investigate basic mechanisms of learning and memory in humans. Our work began in order to understand preserved and impaired learning and memory function in severe amnesic individuals (including patients with bilateral medial temporal lobe damage or Korsakoff's Syndrome). This work culminated in several major scientific papers that bridged the gap between animal and human learning systems. Our laboratory has pioneered the use of the eyeblink classical conditioning paradigm as a marker for a number of behavioral phenomena and structural brain changes that occur in chronic alcoholic individuals. In one set of studies her group is teasing apart the underlying factors that contribute to the heterogeneity of alcoholics' ability to acquire associative responses and, using structural MRI, are attempting to reveal the underlying neuroanatomical substrate(s) mediating preserved and impaired learning.

In a related study they are investigating the conjoint effects of alcohol and alcohol-related hypertension on learning. This study is the first of its kind to examine whether an individuals' ability to learn in this context can be used as a tool to predict alcohol relapse. A second major area of research is the investigation of preserved visual processing in patients with right hemisphere stroke and hemispatial neglect.

Her doctoral dissertation work was the first demonstration that even though patients are unaware of visual information that falls within their neglected visual field, that information is processed and does affect subsequent behavior. This work has sparked a great deal of subsequent investigation to define the limits of unaware visual processing in patients with neglect. Her group is investigating the effectiveness of galvanic vestibular stimulation in minimizing or reversing the impaired performance of patients suffering visual hemispatial neglect. She is investigating complex relationships among genetic and physiological risk factors for dementia, the structural integrity of the brain, and cognitive function in individuals with no overt signs of clinical impairment. Her group demonstrated significant brain changes and subtle cognitive impairment in individuals who present with only risk factors for disease. She is determining whether these subtle brain changes can be detected using the eyeblink conditioning paradigm in which case she might be able to identify individuals at relatively high risk for decline prior to the onset of significant behavioral changes.

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- Xiaohong Joe Zhou, Ph.D.
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**Michael W. Vannier, MD**

Michael W. Vannier, M.D. is Professor of Radiology and Medicine at the University of Chicago. Dr. Vannier, is a radiologist on the staff of The University of Chicago Hospitals, who also was an engineer before he received his medical degree.

A pioneer in the collection and presentation of medical images for 25 years, Vannier studies medical imaging and image processing, the use of imaging in the design and testing of arm and leg prosthetics, and electronic neuroanatomy. Among six image-processing patents Vannier holds are one for a method for gastrointestinal tract unraveling and two for computer-based upper-extremity evaluation. Dr. Vannier serves as editor-in-chief of the International Journal of Computer Assisted Radiology and Surgery. Dr. Vannier was formerly editor-in-Chief of the IEEE Transactions on Medical imaging for 8 years.

Vannier is a fellow of the American Institute of Medical and Biological Engineering, a fellow of the American College of Radiology and a member of the NASA/U.S. Space Foundation Hall of Fame. After receiving his M.D. in 1976, Vannier did his residency in diagnostic radiology at Washington University School of Medicine's Mallinckrodt Institute of Radiology. He joined Mallinckrodt's faculty as an assistant professor in 1982 and became staff radiologist for Barnes Children's Hospital that same year. Vannier became an affiliate professor of system science and mathematics at the College of Engineering in 1984, professor of radiology in 1989 and vice chairman for research at Mallinckrodt in 1993. He was a visiting scientist in the materials and components technology group at Argonne National Laboratory from 1986 to 1987. Vannier become chairman of radiology at the University of Iowa in 1996. He was the Head of the Department of Radiology at the University of Iowa from June 1996 to November 2000, and professor of radiology there from 1996 until April 2004. Dr. Vannier was a special assistant to the Director of the National Cancer Institute Cancer Imaging Program from 2001 to 2003.

Vannier earned his B.S. from Colorado State University and his B.S.M.E. from the University of Kentucky in 1971. He worked as a mechanical engineer while attending medical school at the University of Kentucky and has been a contract employee of NASA and USAF through Computer Sciences Corp. and GTE, among others. He has served as consultant to NATO AGARD, industry, and the medical device industry. Since 1997 he has been a member of the Vital Images, Inc. board of directors (NADDAQ: VTAL).

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**Deborah M. Little, Ph.D.**

**Deborah M. Little, Ph.D.**, is an Associate Professor in the Departments of Neurology and Rehabilitation and Anatomy and Cell Biology at the University of Illinois - Chicago. She also serves as Director of Magnetic Resonance Research in the Department of Neurology. Dr. Little earned her Ph.D. from Brandeis University and completed postdoctoral training in the Center for MR Research at the University of Illinois at Chicago.

#### **Ongoing Research Projects:**

**Category Learning:** Category learning is required for guiding everyday perception, action, and decision making. Category learning is rapid and can be carried out with apparent ease in healthy adults. We study one specific subtype of category learning, prototype-distortion learning. We use a combination of behavioral, eye movement, and fMRI methods to investigate learning. Collaborators: Drs. Raymond Klein (Dalhousie University), Keith Thulborn (UIC), Marilyn Kraus (UIC), and John Sweeney (UIC).

**Aging:** Differential declines in executive functions are a hallmark of normal aging. With normal aging decreases in the volume and density of both gray and white matter disproportionately affect the cortical regions that underlie executive functions. The overall objective of this line of work is to characterize the mechanisms that promote optimal executive function and conversely, suboptimal function, in the elderly. Collaborators: Drs. Pauline Maki (UIC), X. Joe Zhou (UIC), and David Nyenhuis (UIC).

**Dementia:** Differential diagnosis of Alzheimer's disease (AD) from other forms of dementia, particularly vascular dementia (VaD), the second most prevalent dementia, is clinically difficult. The overall goal of the project is determine whether a dissociation between the biological basis of executive function and short term memory can be used to differentiate VaD from AD. Collaborators: Drs. Laura Pedelty and David Nyenhuis.

**Traumatic Brain Injury (TBI) and Pediatric TBI** are defined as an injury to the brain resulting from an external force (i.e., motor vehicle accident, bicycle accidents, falls), with mild being the most common type for severity ratings. The incidence of closed head injury is approximately one million per year, with 90% being classified as mild TBI. The overall goals of the projects are to (1) characterize dysfunction in eye movements and (2) evaluate deficits in learning in adults (Collaborators: M. Kraus) and in children (Collaborators: Drs. Lisa Stanford, Marilyn Kraus, and Raymond Klein).



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## Research

I research scientific visualization and image analysis to improve the biomedical applications of three-dimensional imaging modalities (like MRI and CT). My past research simplified the work of making informative direct volume renderings, inspired by traditional techniques of edge detection. I continue to explore ways of translating mathematical principles of image processing and computer vision to practical methods of detecting, measuring, and understanding biological and anatomical structure in modern imaging data. Much of my current work (in collaboration with colleagues in the Biological Sciences Division) is focused on diffusion MRI, including data inspection, model selection, fiber tractography, feature detection, and tensor analysis. A recent line of work explores particles systems for image feature localization and sampling in four-dimensional image scale-space. All [my research software](#) is open-source, which is vital for creating reproducible methods of computational science.



**Jia-Hong Gao, Ph.D.**

**Research Interests:**

- Functional magnetic resonance imaging and human brain mapping
- Diffusion weighted MRI
- MRI measurements of cerebral blood flow and oxygen metabolism
- Neuronal current MRI

**Education & Training**

- University of Science and Technology of China – B.S. in Physics, 1984
- Yale University – Ph.D. in Applied Physics and Engineering, 1991
- Massachusetts Institute of Technology (MIT) – Postdoc. Training in MRI, 1991-1993

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**Ian T. Foster, Ph.D.**

Ian Foster is Director of the Computation Institute, a joint institute of the University of Chicago and Argonne National Laboratory. He is also an Argonne Senior Scientist and Distinguished Fellow, Chan Soon-Shiong Scholar and the Arthur Holly Compton Distinguished Service Professor of Computer Science.

Ian received a BSc (Hons I) degree from the University of Canterbury, New Zealand, and a PhD from Imperial College, United Kingdom, both in computer science. His research deals with distributed, parallel, and data-intensive computing technologies, and innovative applications of those technologies to scientific problems in such domains as climate change and biomedicine. Methods and software developed under his leadership underpin many large national and international cyberinfrastructures.

Dr. Foster is a fellow of the American Association for the Advancement of Science, the Association for Computing Machinery, and the British Computer Society. His awards include the Global Information Infrastructure (GII) Next Generation award, the British Computer Society's Lovelace Medal, R&D Magazine's Innovator of the Year, and an honorary doctorate from the University of Canterbury, New Zealand. He was a co-founder of Univa UD, Inc., a company established to deliver grid and cloud computing solutions.

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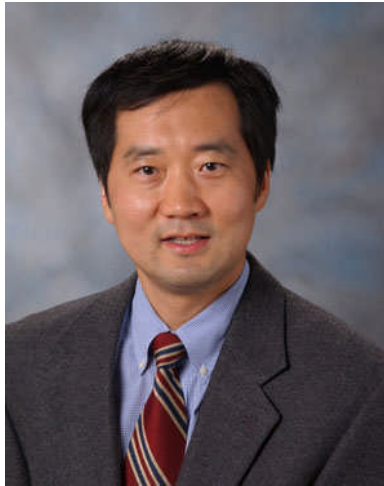
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**Xiaohong Joe Zhou, PhD, DABR**

The research in my group is focused primarily on developing diffusion imaging techniques to improve cancer diagnosis, guide surgery, and monitor treatment efficacy. We are particularly interested in developing non-EPI-based data acquisition techniques to achieve high spatial resolution. With the high resolution capability, we are presently exploring a number of applications, including tracking tumor cell infiltration along the white-matter fiber tracts, early detection of tumor recurrent sites, and probing tissue cellularity change during radiation therapy. Our group is also interested in selective phosphorus imaging at ultra-high field. We are presently developing efficient RF pulses for  $^{31}\text{P}$  selective excitation, and will use the technique to map the 3D distribution of important metabolites, such as phosphorus creatine at 9.4T. The ultimate goal of this project is to develop a robust metabolic imaging marker for human applications.

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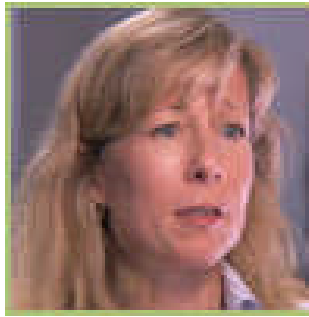
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**Marilyn F. Kraus, M.D.**

Marilyn F. Kraus, M.D. has been an Associate Professor of Psychiatry and Neurology at the University of Illinois-Chicago, and will soon join the faculty at Northwestern University. She has been a senior research faculty member of The Center for Cognitive Medicine at UIC. As a neuropsychiatrist, her area of expertise both clinically and in research for over ten years is the evaluation and neuropharmacologic treatment of neurobehavioral (cognitive, mood and behavior) disorders that result from brain injury. Her research focuses on neuropharmacologic interventions to improve function after traumatic brain injury (TBI), using functional brain imaging and oculomotor studies to assess outcomes. She has had multiple publications in this area, and lectures frequently. Most recently she was awarded a five-year K23 research grant from NIMH to study TBI. She also serves on the Professional Healthcare Board of the Midwest Brain Injury Clubhouse (a not-for-profit organization supporting brain injury survivors and families). Marilyn F. Kraus, M.D. is an Associate Professor of Psychiatry and Neurology. She is a senior research faculty in The Center for Cognitive Medicine. As a neuropsychiatrist, her area of expertise both clinically and in research for over ten years is the evaluation and neuropharmacologic treatment of neurobehavioral (cognitive, mood and behavior) disorders that result from brain injury. Her research focuses on neuropharmacologic interventions to improve function after traumatic brain injury (TBI), using functional brain imaging and oculomotor studies to assess outcomes. She has had multiple publications in this area, and lectures frequently. Most recently she was awarded a five-year K23 research grant from NIMH to study TBI. She also serves on the Professional Healthcare Board of the Midwest Brain Injury Clubhouse (a not-for-profit organization supporting brain injury survivors and families).

#### The Role of Diffusion Tensor Imaging in Traumatic Brain Injury

Over 2.5 million Americans live with disabilities related to traumatic brain injury (TBI). For these patients, neurobehavioral deficits are the most common cause of disability. The neuropathology of TBI often involves diffuse axonal injury, or damage to the white matter of the brain that occurs when the head is rapidly accelerated or decelerated. Diffuse axonal injury is difficult to detect using traditional imaging techniques, but in some cases of TBI, it is the only significant pathology. Diffusion tensor imaging (DTI) is a version of magnetic resonance imaging (MRI) that is being explored as a means of imaging the white matter of the brain. Researchers hope that DTI will someday become part of a more standardized methodology for evaluating and treating patients who have experienced TBI.

DTI takes advantage of the fact that water molecules in the brain diffuse at different rates in different tissues. In more structured tissues, water molecules diffuse more slowly. By measuring the rate of diffusion in many directions from a single point, one can calculate a tensor for that point, and by calculating tensors for many different points, one can create a three-dimensional image of the brain's structure. An important value for any given point in the brain is the fractional anisotropy of that point. Fractional anisotropy values range from zero to one, and the higher the

value, the more ordered the tissue. From this information, it is possible to mathematically recreate much of the brain's neuroanatomy.

To study the usefulness of DTI, researchers led by Marilyn Kraus, MD, of the University of Chicago studied 18 healthy volunteers and 37 people with varying degrees of TBI. They analyzed 13 areas of the brain, and they found that the fractional anisotropy value for each area was lower for patients with moderate to severe TBI than for healthy volunteers. This difference seems to reflect structural damage in the brains of the patients with TBI. The researchers also found the white matter load, a gross measure of white matter damage, increased with the severity of TBI. Finally, they noticed differences in radial and axonal diffusivity that may someday help scientists differentiate between myelin-related problems and direct axonal injury. Taken together, these results suggest that DTI is a useful technique for evaluating the severity of TBI.

Reference: Kraus MF, Susmaras T, Caughlin BP, Walker CJ, Sweeney JA, Little DM. White matter integrity and cognition in chronic traumatic brain injury: a diffusion tensor imaging study. *Brain*. 2007 Oct;130(Pt 10):2508-19.

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AIMBE report to USAMRMC-TATRC Award #: W81XWH-08-1-0125

AIMBE- Military Collaboration: Bioengineering Challenges of Brain Trauma Conference on February 20, 2008 – [http:// handle.dtic.mil/100.2/ADA482037](http://handle.dtic.mil/100.2/ADA482037)



### **Anthony M. Pacifico, Ph.D.**

Dr. Anthony Pacifico obtained his Ph.D. in Biochemistry from the Graduate School of the City University of New York at Hunter College. His thesis research focused on the development of optical methods for detecting changes in cellular metabolism with applications towards molecular pathology. Following the completion of his doctoral research, Dr. Pacifico became a postdoctoral fellow at the National Institute of Alcohol Abuse and Alcoholism (NIAAA). Using a combination of NMR and Fluorescence Polarization methods, Dr. Pacifico conducted biophysical studies into the nature of G-Protein Coupled Receptor signal transduction with a focus on protein-lipid interactions. The research he conducted at the NIAAA completed his training in optical imaging methods of live cells and biological systems.

Upon completion of his laboratory training, Dr. Pacifico became part of the management team at the Army's Prostate Cancer Research Program, as facilitated by the Congressionally Directed Medical Research Programs (CDMRP). Dr. Pacifico assisted in the management of the program's day-to-day administrative needs and provided technical guidance to grants officer representatives. Dr. Pacifico also performed similar services for the Army's Neurofibromatosis and Tuberous Sclerosis Research Programs at CDMRP.

Currently, Dr. Pacifico is the portfolio manager for the Medical Imaging Technologies Portfolio at the Telemedicine and Advanced Technology Research Center. The portfolio currently contains 32 active projects, to which he provides oversight. This portfolio is currently worth approximately \$169.5M. Dr. Pacifico is directly accountable for the management of over 20 of these projects ranging in technological scope from optical imaging to radiation oncology. Additionally, Dr. Pacifico also oversees several studies on Parkinsonism with respect to new imaging agents for this disease. Generally, Dr. Pacifico manages research that addresses some of the concerns of the traumatic brain injury, cancer and trauma research communities. In addition to his interests in spectroscopy and radiology, one of Dr. Pacifico's other research interests is the medicinal chemistry of small molecules.

#### **Selected Publications:**

M. Diem, S. Boydston – White, A. Pacifico and L. Chiriboga, "Distinction between normal and neoplastic human cells and tissues by infrared microspectroscopy," in *Spectroscopy of Biological Molecules: New Directions*, J. Greve, G. J. Puppels and C. Otto, Eds., Kluwer Academic Press, Dordrecht, The Netherlands, 1999, pp. 479-482

M. Diem, L. Chiriboga, A. Pacifico, S. Boydston – White, and H. Yee, "Infrared Microspectroscopy of Cells and Tissue: Infrared Spectral Maps of Liver Tissue," (2000) *Proceedings of SPIE: Biomedical Spectroscopy*, Vol 3918, 28-35



M. Diem, L. Chiriboga, A. Pacifico and H. Yee, "Infrared Microspectroscopy of cells and tissue: Infrared spectra and infrared spectral maps of human tissues," (2000) Inst. Phys. Conf. Ser. 165, 77-78

P.Lasch, M.Boese, A.Pacifico and M.Diem, "FT-IR Spectroscopic Investigations of Single Cells on the Subcellular Level", (2002) Vibrational Spectroscopy, 28(1), 147-157

M.Diem, P.Lasch, L.Chiriboga and A.Pacifico, "Infrared Spectra and Infrared Spectral Maps of Individual Normal and Cancerous Cells", (2002) Biopolymers: Biospectroscopy, 67, 349-353

P.Lasch, A.Pacifico, and M.Diem, "Spatially resolved IR microspectroscopy of single cells", (2002) Biopolymers: Biospectroscopy, 67, 335-338

A.Pacifico, L.Chiriboga, P.Lasch and M.Diem, "Infrared Spectroscopy of Cultured Cells. II. Spectra of Exponentially Growing, Serum-Deprived and Confluent Cells", (2003) Vibrational Spectroscopy, 32, 107-115

A.Pacifico "Terra Incognita: Potential Uses of Optical Spectroscopy for Combat Casualty Care", (2010) RTO/HFM-182 Symposium, Essen, Germany

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**Northwestern University Medical School**



**S. Duke Han, Ph.D.**

My current research interests include neuroimaging and neuropsychological predictors of cognitive decline in aging, neuropsychological and neuroimaging outcomes following mild to moderate traumatic brain injury, genetic factors associated with outcomes following traumatic brain injury, the elucidation of the "executive functions" neuropsychological construct, neurocognitive and neuroimaging outcomes following chemotherapy, and methods of compensating for neurocognitive decline.

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Glenn Stebbins, Ph.D.

Dr. Stebbins' research interests center on the effects of normal and pathological aging on cognitive function in humans. Using advanced neuroimaging (e.g., fMRI, Diffusion Tensor Imaging, SPECT) and behavioral techniques, studies are designed to assess the relationship between structural and functional changes in the CNS and age-related behavioral changes. Specific areas of interest include the contribution of white matter microstructural integrity to cortical and subcortical gray matter function during executive and declarative memory performance.

His current research focuses on four areas: 1) Dissociation of cortical and sub-cortical contributions of executive working memory impairments in patients with movement disorders. 2) Delineation of medial temporal lobe functional activity during declarative memory performance in patients with Alzheimer's disease, mild cognitive impairment, 3). Examining the contribution of "normal appearing" white matter integrity to perceptual motor processing speed and executive working memory performance in patients with ischemic stroke. 4). Decomposing the influence of lesion pathology on cognitive function in patients with multiple sclerosis.

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**Gregory S. Karczmar, PhD**

Dr. Gregory Karczmar is a Professor of Radiology and Medical Physics, and Director of the Magnetic Resonance Imaging/Spectroscopy Laboratory. He teaches imaging physics and biomedical applications of imaging to graduate students and residents. The goal of his research is to develop magnetic resonance methods for early detection of breast and prostate cancer and for image guided therapy.

Dr. Karczmar has been at the University of Chicago since 1989. In addition to his work there, he served on the Research Advisory Committee of the American Cancer Society of Illinois for 10 years, and the Radiation Therapy and Biology Study Section at the National Institutes of Health. He serves on the CALGB imaging committee, and the editorial board of Magnetic Resonance in Medicine. He is co-director of the Advanced Imaging Program at the University of Chicago Comprehensive Cancer Center.

#### EDUCATION

B.S., Reed College in Portland, Oregon, 1977  
M.S., University of California at Berkeley, 1980  
Ph.D., University of California at Berkeley, 1984

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<http://mr.is.uchicago.edu/personnel/gskarczm/karczmar.htm>



**Alice M. Wyrwicz, Ph.D.**

Research in Dr. Wyrwicz's laboratory follows a multidisciplinary approach and is directed toward understanding the relationship between brain function and metabolism under normal and pathological conditions. The techniques of fMRI, multinuclear MRI and spectroscopy are used to monitor non-invasively neural activity, cerebral hemodynamics, neurotransmitter levels and cellular bioenergetics. To obtain a more detailed and comprehensive picture of brain function and pathology, the MR techniques are integrated with information from other methods such as electrophysiology, optical imaging, behavioral analysis, microscopy and biochemical assays. Much of the work involves significant technical developments to allow for systematic, quantitative studies using MR techniques to address specific quantitative hypotheses. Recent developments include techniques that allow for the measurement of neural activation in conscious animals, ultrafast imaging at high magnetic fields, as well as new methods for introducing contrast in MRI based on motional correlation time. Image post processing and analysis of functional data are also areas of active research in the lab and include development of statistical methods for quantitative fMRI data analysis, identification of functional units and thermal and physiological noise removal. In addition, Dr. Wyrwicz's laboratory is also involved with the detection and quantification of evolving neuropathology in transgenic mouse models of Alzheimer's disease (AD) using diffusion tensor imaging (DTI) to measure dendritic pathology as a potential early biomarker of AD.

As the Director of the Center for Basic MR Research (CBMRR), Dr. Wyrwicz is responsible for the administration and operation of the Center which includes providing state-of-the-art MR instrumentation. The CBMRR has a long history of working with investigators throughout the greater Chicago area, Midwest region and extending to the west coast, providing resources for both collaborative and service research projects.

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**Konstantinos Arfanakis, Ph.D.**

Konstantinos Arfanakis, Ph.D. is associate professor at the Illinois Institute of Technology and Director of the Magnetic Resonance Imaging Laboratory. His expertise involves Magnetic resonance imaging (MRI), MRI acquisition and post-processing, diffusion tensor MRI (DTI), and functional MRI (fMRI). The Magnetic Resonance Imaging (MRI) Lab at the Illinois Institute of Technology (IIT) is part of the Medical Imaging Research Center (MIRC) at IIT. The work conducted in the MRI Lab includes the development of MRI data acquisition, image reconstruction, data analysis, and visualization techniques, and the application of these methods for the diagnosis and monitoring of brain disease.

**Education**

B.S., Physics, University of Athens, Greece, 1997

M.S., Medical Physics, University of Wisconsin-Madison, Wisconsin, 1999

Ph.D., Medical Physics, University of Wisconsin-Madison, Wisconsin, 2002

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**Todd B. Parrish, Ph.D.**

Todd Parrish, PhD, director of the Northwestern University Neuroimaging Research Laboratory is a founding member of the Northwestern Cognitive Brain Mapping Group (CBMG) – a team dedicated to investigative brain research. Dr. Parrish's role in the CBMG is to employ state-of-the-art technology, an understanding of MRI physics, and a strong collaboration with other departments to tackle the technical, philosophical and practical problems of brain mapping.

Affiliated Faculty, Biomedical Engineering Department  
Associate Professor, Joint appointment with Radiology (Medical school)  
Director, Center for Advanced MRI (CAMRI) and MR Neuroimaging Research  
Department of Radiology  
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**EDUCATION:**

- University of Minnesota, Minneapolis, Minnesota: PhD 1995, Biophysical Sciences
- Case Western Reserve University, Cleveland, Ohio: MS 1988, Biomedical Engineering

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<http://www.radiology.northwestern.edu/directory/showold/121>

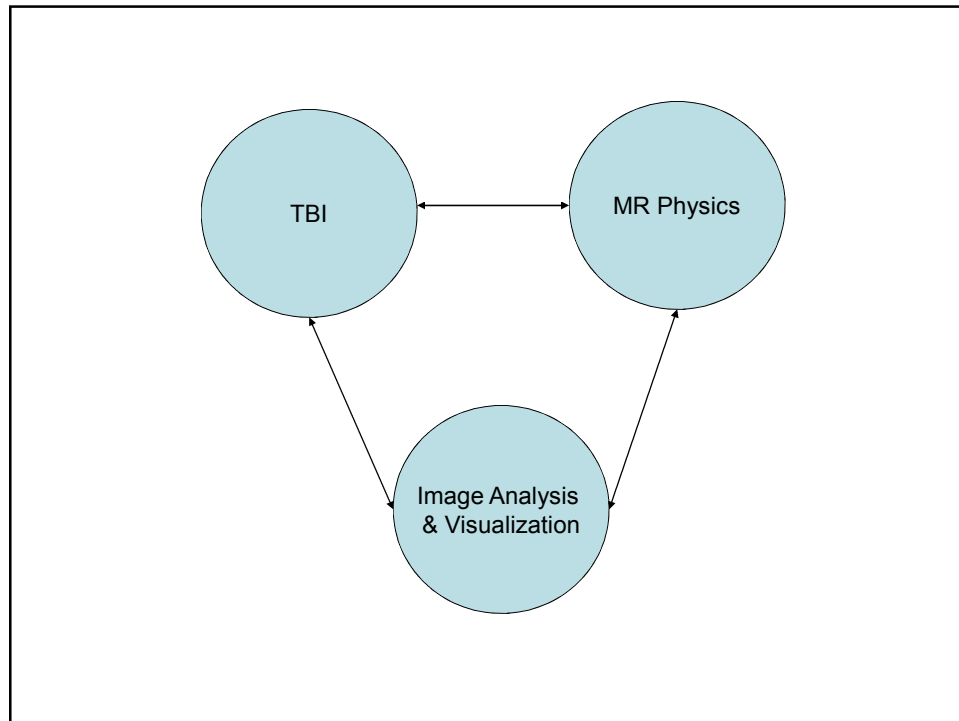


# DMRI of TBI Roadmap Workshop

2-3 June 2010  
Chicago, IL

## Goals

- Establish inter-disciplinary cooperation and collaboration among experts in:
  - Traumatic brain injury & neuroimaging
  - Diffusion MRI physics
  - Advanced visualization and image analysis
- Define the needs and requirements for rapid translation of advanced imaging into Traumatic Brain Injury clinical practice



## Barriers

### IMPEDIMENT

- Data sharing is rare
- Phase 3 trials didn't meet expectations
- Evidence base for imaging is deficient
- Laboratory developments are slow to reach clinical applications
- Tractography is focused on normal cases

### CONSEQUENCES

- Elite groups in image processing and visualization community have no access
- Discourages investment in new trials; promising therapies are delayed
- Low likelihood of imaging could meet requirements for clinical guidelines
- Collaborate on early phase technology trials; use efficient methodology (e.g., Bayesian design)
- Software tools for TBI processing are not optimal; disease agnostic

### REMEDY

- Develop standards; qualify sites; enable federated or central repositories; solve the "rights" problem
- Design and implement trial infrastructure
- Conduct high quality clinical trials with "standard" protocols for image acquisition, quality control, and review / analysis
- Communications & joint planning (short & long term)
- Engage imaging experts in guideline review and development
- Augment models (physical, mathematical, biological) linked to mechanism, repair, plasticity, ...

## Barriers

### IMPEDIMENT

- Lack of interdisciplinary forum on clinical neurotrauma, D-MRI physics, image analysis
- Trauma research is fragmented
- Clinical guidelines exclude imaging
- Disease model
- Tractography is focused on normal cases
- Informatics lags

### CONSEQUENCES

- Fragmentation of effort
- Numerous single center phase 1/2 clinical feasibility studies, but no advanced DMRI of TBI phase 3 trials (multicenter, randomized, blinded)
- Many gov't agencies, industry (medical imaging systems & pharmaceuticals) and academia act independently
- Low likelihood of imaging study if injured
- Simplistic classification (mild/mod/severe) masks key pathophysiological differences
- Cannot measure what's absent from model
- Software tools for TBI processing are not optimal; disease agnostic
- Secondary use of clinical trial data is rare; cannot aggregate heterogeneous data from different sites

### REMEDY

- This and future workshops (?summit meetings)
- Communications & joint planning (short & long term)
- Engage imaging experts in guideline review and development
- Augment models (physical, mathematical, biological) linked to mechanism, repair, plasticity, ...
- Open TBI data to image processing/visualization community so they can optimize tools
- Implement CDEs; develop shared infrastructure / core labs

## Approach

- Interdisciplinary workshop
- Review prior work and current status
- Define needs & requirements
- Multiple perspectives: DoD & government agencies, clinical practice, academia, industry
- Describe and apply best practices
  - Neuroimaging (stroke, Alzheimer's disease, neurooncology)
- Share data

## Why do this now?

- Clinical and public health need is immediate
  - Military blast injuries
  - Auto crash contact injuries; sports
- Promising interventions need testing
- Equipment for advanced MR neuroimaging is widely available
- Advanced MR imaging shows promising results in numerous single center studies
- Progress in translation of advanced imaging methods to clinical applications can be accelerated
- Alternative methods have limitations and DMRI could fill the gap
- Strong public interest, awareness in government, industry, clinical, technical and scientific communities
- The status quo is unsatisfactory

## Breakout Groups

1. TBI, neuroimaging and clinical management  
[Deborah Little & Jam Ghajar]
2. Visualization, image analysis & informatics  
[Ian Foster, Heinz Lemke & Christophe Lenglet]
3. MR Physics  
[Jia-Hong Gao & X. Joe Zhou]

## Motivation

- 1) Lack of standardization & quality control for image acquisition and disease characterization
- 2) Difficulty in extracting quantitative measures of disease presence and burden
- 3) Limited ability to interpret the results due to insufficient reference data and norms.

## Process

- World-leading authorities in diffusion MRI physics and data acquisition, applied mathematics and computer science devoted to analysis of diffusion MRI scans, and traumatic brain injury clinical management experts meet and establish inter-group communications
- The requirements defined by clinical experts will be delivered directly to those who develop the tools needed to conduct and evaluate examinations,
- The boundaries between individual institutions, scanner manufacturers, and government agencies which impair data sharing and standardization will be identified and remedies recommended.

## Questions

- Why diffusion MRI?
- Which diffusion MRI method? (there are many)
- How to ensure high quality data? (QARC)
- Site qualification? (criteria and verification process)
- Shared repository. Will anyone use it?
  - Federated vs. Central archive
  - Security; HIPAA; long term follow-up
  - Investigator rights? And rights of other parties?

## Questions

- MIAME = “Minimum Information Associated with a Microarray Experiment”
  - Should D-MRI community have one for TBI data?
  - If so, what should it contain?
- What does your community need?
  - 3 communities (TBI, MR physics, Image analysis)
  - What does TBI need from MRP?
  - What does IA need from TBI?
  - What does MRP need from TBI?
  - Etc., etc. (all permutations)



## Final reports

- 1. TBI – D. Little
  - Panel: X. Pennec, P. van Zijl, J. Schenck
  - Alternate: S. Rajan
- 2. Visz & image analysis – I. Foster
  - Panel: T. McAllister, J. Whyte, S. Rao
  - Alternate: G. Liu
- 3. MR Physics – J. Gao
  - Panel: R. Deriche, J. Hunter, D. Smith
  - Alternate: J. Bjork

# DMRI of TBI Roadmap Workshop

## Breakout Group Assignments

2-3 June 2010

Chicago, IL

## Breakout Groups

1. TBI, neuroimaging and clinical management  
[Deborah Little & Jam Ghajar]
2. Visualization, image analysis & informatics  
[Ian Foster, Heinz Lemke & Christophe Lenglet]
3. MR Physics  
[Jia-Hong Gao & X. Joe Zhou]



## TBI, neuroimaging and clinical management

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. David F. Moore MD, PhD, Dip PH, MRCP(I)</li> <li>2. Pratik Mukherjee, M.D., Ph.D.</li> <li>3. Thomas W. McAllister, MD</li> <li>4. Stephen Rao, Ph.D. Cleveland Clinic</li> <li>5. Doug Smith, MD University of Pennsylvania</li> <li>6. Jill V. Hunter M.B. B. S., M.R.C.P (U.K.), F.R.C.R. Baylor College of Medicine</li> <li>7. Harvey S. Levin, PhD Baylor College of Medicine</li> <li>8. Mary R.T. Kennedy, PhD, CCC University of Minnesota</li> <li>9. Jamshid Ghajar MD, PhD, FACS President, Brain Trauma Foundation</li> <li>10. Thomas A. Gennarelli, MD Medical College of Wisconsin</li> <li>11. Christine L. Mac Donald, PhD; Washington University St Louis</li> <li>12. John Whyte, MD, Ph.D. Director of Moss Rehabilitation Research Institute</li> </ol> | <ol style="list-style-type: none"> <li>13. Carole L. Palumbo, Ph.D. VA Boston Healthcare System (VABHS)</li> <li>14. James Bjork, Ph.D. National Institute of Drug Abuse/NIH</li> <li>15. Stuart Hoffman, PhD U.S. Department of Veterans Affairs (122)</li> <li>16. Karen A. Tong, M.D. Loma Linda University Medical Center</li> <li>17. David H. Keeler Marine Corps Systems Command</li> <li>18. Donald Marion, MD, MSc Walter Reed Army Medical Center</li> <li>19. Elizabeth C. Leritz, Ph.D. VA Medical Center, Boston, MA</li> <li>20. Randall R. Benson, M.D. , Wayne State University School of Medicine</li> </ol> |
|---|---|
21. Gerard Riedy, MD, PhD - Walter Reed Army Medical Center
  22. A. Gregory Sorenson, MD - Mass General Hospital

## Visualization, image analysis & informatics

- |  |   |
|--|---|
| <ol style="list-style-type: none"> <li>1. Susumu Mori, M.S., Ph.D. Johns Hopkins University</li> <li>2. Hal Cecil Charles, Ph.D. Duke University</li> <li>3. Christophe Lenglet, Ph.D. University of Minnesota</li> <li>4. Ross T. Whitaker, PhD University of Utah</li> <li>5. Manbir Singh, Ph.D. University of Southern California</li> <li>6. James C. Gee, PhD University of Pennsylvania</li> <li>7. Charles R. Meyer, Ph.D. University of Michigan</li> </ol> | <ol style="list-style-type: none"> <li>8. David H. Laidlaw, Ph.D. Brown University</li> <li>9. Laurence (Larry) Clarke, Ph.D. NIH/National Cancer Institute</li> <li>10. Carl-Fredrik Westin, PhD Harvard Medical School</li> <li>11. Andrew I.R. Maas, M.D., Ph.D. University Hospital Antwerp</li> <li>12. Alexander Leemans, Ph.D. University Medical Center Utrecht</li> <li>13. Heinz U. Lemke, PhD Institute of Advanced Studies University of Munich</li> <li>14. Xavier Pennec, Ph.D. Asclepios Project-Team INRIA, Sophia-Antipolis</li> <li><del>15. David H. Keeler - Marine Corps Systems Command</del></li> <li>16. Rachid Deriche, Ph.D. ATHENA Team Leader, INRIA, Sophia-Antipolis</li> </ol> |
|--|---|

## MRI Physics

1. Ponnada A. Narayana, Ph.D., M.Sc.
2. Peter C. M. van Zijl, Ph.D. Kennedy Krieger Institute
3. Adam W. Anderson, Ph.D. Vanderbilt University
4. Roland Bammer, Ph.D. Stanford University
5. Chunlei Liu, Ph.D. Duke University
6. Jianhui Zhong, Ph.D. University of Rochester Medical Center
7. Norbert Schuff, Ph.D. San Francisco VA Medical Center
8. Carlo Pierpaoli, M.D., Ph.D. (NICHD)National Institutes of Health
9. Sunder Rajan, Ph.D. FDA/CDRH/ODE
10. John M. Moreland, PhD -National Inst of Standards and Technology (NIST)
11. Guoying Liu, Ph.D. National Inst of Biomed Imaging and Bioengrg / NIH
12. John F. Schenck, M.D., Ph.D. GE Corporate R & D Center
13. Andrew L. Alexander, Ph.D. University of Wisconsin
14. Ken Sakaie, Ph.D. Imaging Institute, Cleveland Clinic
15. M. Alex Dresner, Ph.D. Philips HealthCare, Inc.
- ~~16. Rachid Deriche, Ph.D. ATHENA Team Leader, INRIA, Sophia-Antipolis~~
17. Mark J. Lowe, Ph.D. Imaging Institute Cleveland Clinic
18. Srirama Swaminathan, Ph.D, MBA Philips Healthcare

## Breakout Group Schedule – Day 1

- Welcome & introductions
- Review of the process
- Nomination of delegates to B and C groups from A group
- Statement of objectives; review of agenda
- Question 1 & discussion
- Question 2 & discussion
- .... Question n & discussion
- Tomorrow's agenda

## Breakout Group Schedule – Day 2

- Welcome and introduction of delegates from groups B and C
- Group B requirements
- Discussion and preparation of response
- Group C requirements
- Discussion of preparation of response
- Summary & review of all suggested responses
- Consensus, if possible
- Preparation for plenary; Review of draft recommendations

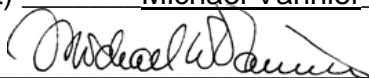
# Breakout Group “A” Schedule

3:30 PM	DAY 1 [Group A meets alone]	8:00 AM	DAY 2 [Delegates from Groups B & C join Group A]
3:30	Welcome & introductions	8:00	Welcome & introductions of delegates from groups B & C
3:40	Review of the process	8:10	Group B requirements
3:50	Statement of objectives; review of agenda	8:20	Discussion & preparation of response
4:00	Nomination of delegates to groups B & C from group A	8:45	Group C requirements
4:10	Question 1 & discussion	8:55	Discussion & preparation of response
	. . .	9:15	Summary & review of suggested responses
5:25	Question n & discussion	9:30	Consensus, if possible
5:30	Summary of results	9:45	Summary & review of all recommendations
5:40	Review of Day 2 agenda		
5:45	Session closes	10:00	Breakout sessions end

## Principal Investigator Assurance

- ◆ I assure that I have involved the Facility Safety Director/Manager in the planning of this research proposal, discussed with him/her all aspects of the proposal that relate to occupational health and safety, and will help him/her prepare the annual Facility Safety Plan Status Report.
- ◆ I assure that I will comply with my institution's safety program and its requirements.
- ◆ I understand that I am directly responsible for all aspects of safety and occupational health specific to my research protocol.
- ◆ I assure that I will report to the Facility Safety Director/Manager any changes in the safety or occupational health practices due to changes in my originally planned research.
- ◆ I assure that hazards associated with my research have been identified eliminated and/or controlled.
- ◆ I assure that all Facility Safety Plan requirements are in compliance with Local, State and Federal general industry standards.
- ◆ If applicable, I assure Biological research programs will follow the recommended guidelines established in the latest editions of the CDC-NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL); Army Regulation 385-10, Chapter 20 (Biological Safety); and DA Pamphlet 385-69 (Safety Standards for Microbiological and Biomedical Laboratories).

Name of Principal Investigator (print) Michael Vannier

Signature of Principal Investigator 

Date: 10/19/2010

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### Facility Safety Director/Manager Assurance

- ♦ I assure that this institution has an existing institutional safety and occupational health program that meets appropriate Federal, State, and Local regulations as required by law, as well as the National Institute of Health Guidelines for Research Involving DNA Molecules, dated April 2002.
- ♦ I assure that all hazards associated with the research laboratories have been identified, eliminated, and/or controlled in such a manner as to provide for a safe research laboratory environment.
- ♦ I accept full responsibility for submitting the annual **Facility Safety Plan Status Report** including significant changes in facility, safety equipment, and safety procedures by fax to 301-619-6627, by e-mail to USAMRMC MPMC SS, by mail to Commanding General, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-SS, 504 Scott Street, Fort Detrick, MD 21702-5012.
- ♦ I assure that I have consulted with all current PI's holding USAMRMC awards concerning this institution's safety policies and procedures and will consult with all future PI's holding USAMRMC awards concerning this institution's safety policies and procedures.
- ♦ I assure that all Facility Safety Plan requirements are in compliance with Local, State and Federal general industry standards.
- ♦ If applicable, I assure Biological research programs will follow the recommended guidelines established in the latest editions of the CDC-NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL); Army Regulation 385-10, Chapter 20 (Biological Safety); and DA Pamphlet 385-69 (Safety Standards for Microbiological and Biomedical Laboratories).
- ♦ Use of etiologic agents as defined below: ☐ Yes ☐ No  
 "Etiologic agent = a viable microorganism, or its toxin which causes or may cause human disease, and includes those agents and includes those agents classified as Risk Group 2 or higher as defined in the latest edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL)."

Krista C Cooley  
 Name of Institution's Safety Director/Manager (print)

Krista C Cooley  
 Signature

10/8/10  
 Date

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